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No. 78-911

IN THE

Supreme Court of the United States

October Term, 1978

INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION, MANUFACTURING CHEMISTS ASSOCIATION, NATIONAL PETROLEUM REFINERS ASSOCIATION, AMERICAN PETROFINA INCORPORATED, ATLANTIC RICHFIELD COMPANY, CITIES SERVICE COMPANY, CONTINENTAL OIL COMPANY, DELTA OIL COMPANY, EXXON CORPORATION, GULF OIL COMPANY, MARATHON OIL COMPANY, PHILLIPS PETROLEUM COMPANY, SHELL OIL COMPANY, SOUTH HAMPTON OIL COMPANY, STANDARD OIL COMPANY (Indiana), STANDARD OIL COMPANY OF OHIO, SUN OIL COMPANY OF PENNSYLVANIA, SUN OIL COMPANY OF DELAWARE, TEXACO INC., UNION OIL COMPANY OF CALIFORNIA

RUBBER MANUFACTURERS ASSOCIATION, INC., FIRESTONE TIRE & RUBBER COMPANY, GENERAL TIRE & RUBBER COMPANY, B. F. GOODRICH COMPANY, GOODYEAR TIRE & RUBBER COMPANY

E. I. DUPONT DE NEMOURS AND COMPANY

ARMSTRONG RUBBER COMPANY AND UNIROYAL COMPANY

INDEPENDENT PETROLEUM ASSOCIATION OF AMERICA

AMERICAN IRON AND STEEL INSTITUTE, BETHLEHEM STEEL CORPORATION, CYCLOPS CORPORATION, JONES AND LAUGHLIN STEEL CORPORATION, NATIONAL STEEL CORPORATION, REPUBLIC STEEL CORPORATION, SHENANGO INCORPORATED, UNITED STATES STEEL CORPORATION
and

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION,
Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

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Petitioner Industrial Union Department, AFL-CIO (hereinafter "IUD") respectfully prays that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Fifth Circuit entered in this case on October 5, 1978.

OPINIONS BELOW

The opinion of the court of appeals is reported at 581 F.2d 498 and is reprinted as Appendix A in a separate Appendix accompanying this petition. The Occupational Safety and Health Standard governing "Occupational Exposure to Benzene" and the Statement of Reasons of the Secretary of Labor issued with the standard are reported at 43 Fed. Reg. 5918 and are reprinted as Appendices B and C. The amendment to the standard is reported at 43 Fed. Reg.

27962 and is reprinted as Appendix D. The order of the court of appeals consolidating the petitions to review the amendment with the petitions to review the standard is unreported and is reprinted as Appendix E. The judgment of the court of appeals is reprinted as Appendix F.

JURISDICTION

The Court of Appeals' judgment issued on October 5, 1978. (App. F). On November 1, 1978, the Court of Appeals consolidated the petitions to review the amendment to the standard with the petitions to review the standard (App. E). The jurisdiction of this Court is invoked pursuant to 28 U.S.C. § 1254(1).

QUESTION PRESENTED

The Occupational Safety and Health Act delegates to the Secretary of Labor the power to adopt standards governing the exposure of working men and women to toxic materials and directs the Secretary to "set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life." In enacting this law, did Congress intend to preclude the Secretary from promulgating a regulation limiting workers' exposure to a proven carcinogen until such time as substantial evidence becomes available from which to quantify the number of lives that would be saved by the proposed regulation?

STATUTORY PROVISIONS INVOLVED

The Occupational Safety and Health Act of 1970, 29 U.S.C. § 651 et seq. provides in pertinent part:

§ 651. Congressional statement of findings and declaration of purpose and policy

(a) The Congress finds that personal injuries and

illnesses arising out of work situations impose a substantial burden upon, and are a hindrance to, interstate commerce in terms of lost production, wage loss, medical expenses, and disability compensation payments.

(b) The Congress declares it to be its purpose and policy, through the exercise of its powers to regulate commerce among the several States and with foreign nations and to provide for the general welfare, to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources—

* * *

(3) by authorizing the Secretary of Labor to set mandatory occupational safety and health standards applicable to businesses affecting commerce, and by creating an Occupational Safety and Health Review Commission for carrying out adjudicatory functions under this chapter . . .

§ 652. Definitions

* * *

(8) the term 'occupational safety and health standard means a standard which requires conditions or the adoption or use of one or more practices, means methods, operations, or processes reasonably necessary or appropriate to provide safe or healthful employment and places of employment.

§ 655. Standards

(b)

* * *

(5) The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of

the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired.

* * *

(f) Any person who may be adversely affected by a standard issued under this section may at any time prior to the sixtieth day after such standard is promulgated file a petition challenging the validity of such standard with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such standard. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary. The filing of such petition shall not, unless otherwise ordered by the court, operate as a stay of the standard. The determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole.

STATEMENT OF THE CASE

This case concerns the validity of the regulation governing occupational exposure to benzene promulgated by the Secretary of Labor ("the Secretary") pursuant to the Occupational Safety and Health Act of 1970, 29 U.S.C. § 651 et seq. ("the Act"). Benzene is one of the most widely produced chemicals in the United States, and the amount produced is rapidly increasing. Most benzene is used as an ingredient in the production of other organic chemicals; the remaining amount is used primarily in the manufacture of detergents, pesticides, solvents and paint removers, and as a component of motor fuels. Benzene has long been recognized as a toxic substance.

Shortly after the Act became effective, the Secretary promulgated a "national consensus standard" limiting the amount of benzene to which employers could expose their

employees.[1] Under that standard a permissible exposure level for benzene was established of 10 parts per million (ppm) as an 8-hour time weighted average, with a maximum permissible peak concentration of 50 ppm for 10 minutes in any 8-hour period. This standard was adopted from the consensus standard developed by the American National Standards Institute, and was based on evidence linking benzene to certain blood disorders such as aplastic anemia, but not on what was then considered the possible carcinogenic effects of exposure to benzene.

In August, 1976, the National Institute for Occupational Safety and Health ("NIOSH"), which was established by § 22 of the Act, 29 U.S.C. § 671, and directed to "develop and establish recommended occupational safety and health standards," found "the accumulated evidence to be conclusive at this time that benzene is leukemogenic"—*i.e.*, that it causes leukemia, an irreversible, fatal cancer of the white blood cells. In accordance with its conclusion, NIOSH recommended that the existing consensus standard (which, as noted above, was not based on the leukemogenic effects of benzene exposure), be modified to take account of the newly-

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[1] Section 3(9), 29 U.S.C. § 652(9), defines a "national consensus standard" as:

> any occupational safety and health standard or modification thereof which (1) has been adopted and promulgated by a nationally recognized standards-producing organization under procedures whereby it can be determined by the Secretary that persons interested and affected by the scope or provisions of the standard have reached substantial agreement on its adoption, (2) was formulated in a manner which afforded an opportunity for diverse views to be considered and (3) has been designated as such a standard by the Secretary, after consultation with other appropriate Federal agencies.

Under § 6(a), 29 U.S.C. § 655(a) the Secretary was required "as soon as practicable" within the first two years after the Act became effective to promulgate as a legally binding regulation "any national consensus standard" unless the Secretary determined that the promulgation of such a standard "would not result in improved safety or health for specifically designated employees."

obtained evidence establishing benzene as a leukemogen. Specifically, NIOSH recommended that "since it is not possible at this time to establish an exposure level at which benzene may be regarded to be without danger . . . exposure to benzene be kept as low as possible." NIOSH concluded that 1 ppm was the lowest level to which exposure could be reduced "at this time" and suggested that the exposure limit be set at that level.[2] NIOSH further recommended that an emergency temporary standard be promulgated[3] establishing the 1 ppm limit.

On May 3, 1977, the Secretary issued an emergency temporary standard as proposed by NIOSH.[4] Shortly thereafter the Secretary, as required by § 6(c) (3) of the Act, 29 U.S.C. § 655(c) (3), initiated rulemaking proceedings to develop a new, permanent standard. A proposed rule, incorporating the emergency temporary standard, was published in the Federal Register along with a lengthy explanation, incorporating the preamble to the temporary standard.

[2] Two years earlier, NIOSH had concluded that "the possibility that benzene can induce leukemia cannot be dismissed," but had not recommended any change in the national consensus standard in light of what it viewed as the then-uncertain link between benzene and leukemia.

[3] Section 6(c)(1) of the Act, 29 U.S.C. § 655(c)(1), directs the Secretary to adopt, without going through rulemaking proceedings, "an emergency temporary standard to take immediate effect upon publication . . . if he determines (A) that employees are exposed to grave danger from exposure to substances or agents determined to be toxic or physically harmful . . . and (B) that such emergency standard is necessary to protect employees from such danger."

[4] The emergency temporary standard was never enforced. Petitions for review of the standard were filed first in the District of Columbia and then in the Fifth Circuit. The Fifth Circuit issued a stay of the standard pending the decision of the D.C. Circuit as to whether the petition filed with it was premature. That decision was not issued for almost six months, at which time the statutory life of the emergency standard had virtually lapsed. See 29 U.S.C. § 655(c)(2),(3).

42 Fed. Reg. 27452-59. At the same time, notice was given that an informal public hearing would be conducted beginning on July 19, 1977, and interested persons were invited to "submit written data, views and arguments" and "oral testimony" with respect to the issues raised by the emergency standard and the proposed permanent standard. *Id.* at 27459.

The public hearings on the proposed standard were held as scheduled.[5] A total of 95 persons testified, including representatives of and medical and technical experts retained by various employers and labor organizations, and independent experts from public health organizations (such as representatives of NIOSH and of the National Cancer Institute) presented by the Occupational Safety and Health Administration ("OSHA"). Each witness was subject to cross-examination by all interested parties. The hearings extended over seventeen hearing days, at the end of which interested parties were provided with an opportunity to submit additional written evidence and briefs. In all, the hearing transcript consumes over 3400 pages, and in addition over 1400 exhibits and comments were made a part of the record.

Although Congress anticipated that the Secretary would be able to issue standards within 60 days after the close of the standard-setting record, see 29 U.S.C. § 655(b)(4), the Secretary took over four months to study the benzene rec-

[5] The Act does not specify the nature of the informal hearing required by § 6(b)(3), 29 U.S.C. § 655(b)(3). By regulation the Secretary has provided that:

> The oral hearing shall be legislative in type. However, fairness may require an opportunity for cross-examination on crucial issues. The presiding officer is empowered to permit cross-examination under such circumstances. The essential intent is to provide an opportunity for effective oral presentation by interested persons which can be carried out with expedition and in the absence of rigid procedures which might unduly impede or protract the rulemaking process. 29 C.F.R. § 1911.15 (a)(2).

ord. On February 10, 1978, the Secretary promulgated a new benzene standard lowering the permissible exposure level to what he determined to be the lowest feasible level—1 ppm. At the same time, the Secretary issued a comprehensive Statement of Reasons which takes up 45 pages in the Federal Register. App. at 67a-251a.[6]

In the Statement of Reasons the Secretary made a number of findings and conclusions of critical importance to this case. First, the Secretary found that

> "the accumulated evidence is conclusive that benzene exposure is causally related to the induction of leukemia (a cancer of the blood-forming system), various cytopenias (decreased levels of a formed element [red cells, white cells, and platelets] in the circulating blood), aplastic anemia (a non-functioning of bone marrow) and to the development of chromosomal aberrations." [*Id.* at 81a].

With particular regard to the leukemogenic properties of benzene, the Secretary reported that from the published literature alone one scientist had been able to identify at least 250 cases in the United States in which workers had contracted leukemia as the result of benzene exposure. *Id.* at 121a. The Secretary further reported that a series of retrospective studies of groups of benzene-exposed workers had found the rate of leukemia deaths among these persons to be many times higher than the leukemia death rate in the population as a whole. *Id.* at 99a-119a. And the Secretary correctly noted that even "[i]ndustry participants in the benzene rulemaking did not, for the most part, challenge benzene's leukemogenicity." *Id.* at 123a.

[6] On June 27, 1978, the Secretary published in the Federal Register an amendment to the standard which, *inter alia*, exempted from the standard all work operations in which the exposure to benzene derives solely from liquids containing .5% or less of benzene by volume. App. at 252a. Petitioner herein and several of the respondents herein filed petitions seeking review of the amendment. Subsequent to the issuance of its decision invalidating the standard the court *sua sponte* consolidated the petitions to review the amendment with the petitions to review the standard, thereby disposing of the former petitions. The judgment challenged here thus encompasses the dismissal of IUD's petition to review the amendment.

With respect to the industry participants' contention that at low exposure levels benzene is safe, the Secretary concluded, as had NIOSH, see p. 6, *supra*, and numerous experts quoted by the Secretary, App. at 184a-86a,[7] that there is no evidence to support that claim. *Id.* at 123a-25a, 182a-87a. The Secretary explained that because of the long latency period for cancers generally and the variability in individual sensitivity to carcinogens, determining whether low levels of benzene are harmless would require studying the mortality rates of large groups of workers who could be shown to have been exposed to low levels of benzene up to 30 years earlier. The Secretary found that "to reconstruct and define employees' exposure retrospectively" and then to trace the exposed population for a prolonged period of time is "extremely difficult" and that because of these and other difficulties there are no reliable studies. *Id.* at 124a, 182a. Indeed, the Secretary concluded that "there does not exist an adequate scientific basis for establishing the quantitative dose-response relationship between exposure to benzene and the induction of leukemia and other blood diseases [*i.e.*, the number of persons who will be made ill by various incremental doses of benzene]." *Id.* at 160a. But the Secretary did find that there is "general agreement that a dose-response relationship is likely to exist; that is, exposure to higher doses carries with it a higher risk of cancer, and conversely, exposure to lower levels is accompanied by a reduced risk, even though a precise quan-

[7] The Secretary quoted reports in the record by the National Cancer Institute's Ad Hoc Committee on the Evaluation of Low Levels of Environmental Carcinogens, the International Workshop on the Toxicology of Benzene, the MAK-Werte Working Group, and the testimony of Drs. Kraybill (of the National Cancer Institute), Goldwater (testifying for respondent Manufacturing Chemists Association) Goldstein, and Aksoy.

titative relationship cannot be established." *Id.* Thus, the Secretary concluded that it "is apparent . . . that a decrease in exposure level and/or duration will result in a decreased risk of leukemia." *Id.* at 183a.

Based on all of these findings—and given the large number of workers exposed to benzene—the Secretary decided, as he has consistently done in regulating carcinogens, that "prudent public health policy" requires that the permissible exposure level for benzene be set as low as feasible. The Secretary concluded that the decreased risk to the health of workers that would be achieved by so reducing the exposure level justified this decision.

The Secretary recognized that the absence of evidence as to the precise effects of exposure to low levels of benzene "place[d] the estimation of benefits [from the reduced exposure level] on 'the frontiers of scientific knowledge.'" *Id.* at 160a. Even without an exact estimate of the number of lives to be saved, however, the Secretary was still able to conclude, based on the evidence establishing that reducing the exposure to benzene would reduce the risk of leukemia and other blood disorders faced by thousands of workers, that the lower exposure level is "necessary in order to effectuate the statutory purpose of the Act and to adequately protect employees from the hazards of exposure to benzene." *Id.* at 163a.

Immediately upon the issuance of the standard (and Statement of Reasons) a number of trade associations representing producers and users of benzene as well as individual companies that produce or use benzene[8] sought review of the standard under § 6(f) of the Act, 29 U.S.C. § 655(f).[9] The cases were consolidated in the Fifth Circuit

[8] All parties who sought review of the standard below are listed as respondents on the cover of this petition.

[9] Section 6(f) provides:

> (f) Any person who may be adversely affected by a standard issued under this section may at any time prior to the sixtieth day after such standard is promulgated file a petition challenging the validity of such standard with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such standard. . . . The determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole.

and were heard on an expedited basis. On October 5, 1978, a division of that Circuit issued its opinion vacating the permissible exposure level for benzene, and with it the entire benzene standard.

In overturning the benzene standard the court of appeals did not disturb the Secretary's findings as to the dangers posed by benzene, the absence of a known safe exposure level to this poison, or the beneficial impact that a reduction of the exposure level would have. To the contrary, the court acknowledged that the Secretary's conclusion "that the standard is likely to result in benefits is not unsupported." App. at 18a. The court concluded that the record "provides substantial evidence which would support the finding that exposure to benzene at the present level of 10 ppm poses some leukemia risk," *id.*, and the court further found that "[t]he general agreement in the scientific community that exposure to carcinogens at low levels is safer than exposure at higher levels permits the further factual deduction that reducing the permissible exposure limit from 10 ppm to 1 ppm will result in some benefits," *id.*[10] What the court held, quite simply, was that these findings by the Secretary were not sufficient to sustain the regulation. Rather, the court concluded, the Secretary also was required to make a specific "estimate of benefits supported by substantial evidence." *Id.* at 19a-21a. Since the Secretary had not done so because in his view present scientific knowledge did not permit such an estimate, the court found that the standard could not survive.

[10] The court also left undisturbed the Secretary's finding that reducing benzene exposure to 1 ppm was feasible.

The court of appeals candidly acknowledged the necessary consequence of its decision: it has disabled OSHA from adopting a standard more stringent than the preexisting national consensus standard for benzene, notwithstanding the fact that in the court's own words "exposure to benzene at the present level . . . poses some leukemia risk." The court expressly rejected "OSHA's argument that this standard should be upheld since the lack of knowledge concerning the effects of exposure to benzene at low levels makes an estimation of benefits from reducing the permissible exposure level impossible." *Id.* at 19a. Accordingly, the court concluded that "[u]ntil such estimates [of the extent of benefits expected from reducing the permissible exposure level from 10 ppm to 1 ppm] are possible," OSHA will be barred from acting.[11] *Id.* at 21a,

REASONS FOR GRANTING THE WRIT

I. THE DECISION BELOW IS IN SQUARE CONFLICT WITH DECISIONS OF THREE OTHER CIRCUITS

The Fifth Circuit's decision is in direct conflict with *Industrial Union Department* v. *Hodgson*, 499 F.2d 467 (D.C. Cir. 1974), *Society of Plastics Industry, Inc.* v. *OSHA*, 509 F.2d 1301 (2d Cir.), *cert. denied*, 421 U.S. 922 (1975); and *American Iron and Steel Institute* [*AISI*] v. *OSHA*, 575 F.2d 825 (3rd Cir. 1978). Indeed, the court below recognized this conflict but expressly declined to "attempt to reconcile" its decision "with the cases from other circuits which uphold other standards regulating exposure to carcinogens." App. at 21a. And those cases cannot be so reconciled. For each upheld an OSHA standard limiting exposure to a carcinogen on findings by the Secretary ana-

[11] In the course of so concluding the court dropped the following telling citation: "*But see Society of Plastics Industry, Inc.* v. *OSHA*, 509 F.2d 1301, (2d Cir. 1975)." *Society of Plastics Industry*, the decision upholding OSHA's regulation of vinyl chloride, is discussed at pp. 14-15 *infra*.

lytically indistinguishable from the findings on which the standard at issue here was based.[12]

In *Industrial Union Department, supra,* the District of Columbia Circuit reviewed the validity of an OSHA standard governing exposure to asbestos dust. The standard was promulgated at a time when, in the court's words, "reliable data [was] not available with respect to the precisely predictable health effects of various levels of exposure to asbestos dust." 499 F.2d at 475. Unlike the court below, which held (with respect to benzene) that the Secretary was disabled from acting until such evidence becomes available, the District of Columbia Circuit unanimously found no infirmity in the regulation. Writing for the court, Judge McGowan reasoned that in delegating authority to promulgate occupational health standards to the Secretary, Congress had intended to authorize the Secretary to make decisions which implicate questions "on the frontiers of scientific knowledge" as to which "insufficient data is presently available to make a fully informed factual determination." *Id.* at 474. With respect to such decisions, Judge McGowan concluded that Congress had vested in the Secretary the power to make "a prediction based upon pure legislative judgments." *Id.* Accordingly, the court found the asbestos standard law-

[12] The decision below is also inconsistent with decisions that have been rendered under numerous other statutes upholding an administrator's authority to regulate carcinogens without waiting for conclusive evidence establishing the extent of harm that the carcinogen is likely to cause at the levels being regulated and thus the extent of benefits likely to result from the regulation. See, e.g., *Environmental Defense Fund* v. *EPA*, No. 77-1091 at 54-58 (D.C. Cir., Nov. 3, 1978) (Tamm, J.) (Federal Water Pollution Control Act amendments); *Certified Color Manufacturers Ass'n.* v. *Mathews*, 543 F.2d 284, 297-98 (D.C. Cir. 1976) (Wilkey, J.) (Federal Food, Drug and Cosmetic Act); *Ethyl Corp.* v. *EPA*, 541 F.2d 1, 24-25 (D.C. Cir. 1976) (en banc) (Clean Air Act); *Reserve Mining Co.* v. *EPA*, 514 F.2d 492, 527-29 (8th Cir. 1975) (en banc) (Federal Water Pollution Control Act).

ful notwithstanding the absence of evidence as to the extent of the benefits that would be realized, since "the protection of the health of employees is the overriding concern of OSHA," and the Secretary's determination "over strong employer objection [to set] a relatively low limit * * * rests in the final analysis on an essentially legislative policy judgment rather than a factual determination concerning the relative risks of underprotection as compared to overprotection." *Id.* at 475.

In *Society of the Plastics Industry, Inc., supra*, the vinyl chloride case, the Second Circuit reached a decision in accord with *Industrial Union Department* and equally in conflict with the decision below. In *Plastics Industry* the employers challenged the vinyl chloride standard on the ground

> that the available scientific medical evidence does not establish that the 1 ppm exposure level adopted by the Secretary is required by health or safety considerations. They claim[ed] that no proof exists in the record to justify such a low standard, since all of the medical witnesses testified that no one can say whether exposure sure to [vinyl chloride] at low levels was safe or unsafe. [509 F.2d at 1308.]

Writing for the court, the late Mr. Justice Clark rejected that argument, concluding "that the evidence is quite sufficient to warrant the Secretary's choice," notwithstanding the absence of data as to the effects of exposure to low levels of vinyl chloride. *Id.* Mr. Justice Clark explained:

> As in *Industrial Union Department, AFL-CIO* v. *Hodgson, supra*, the ultimate facts here in dispute are 'on the frontiers of scientific knowledge,' and though the factual finger points it does not conclude. Under the command of OSHA it remains the duty of the Secretary to act to protect the workingman, *and to act even in circumstances where existing methodology or research is deficient.* The Secretary . . . has chosen to reduce the permissible level to the lowest detectable one.

> We find no error in this respect. [Emphasis added.] [18]

Finally, in *American Iron and Steel Institute* [*AISI*], *supra*, the Third Circuit, per Judge Rosenn, also upheld an OSHA standard requiring that exposure to a proven carcinogen—in that case coke oven emissions—be reduced to the lowest level that is technically and economically feasible. The Court concluded that the Secretary's findings that coke oven emissions are carcinogenic and that there is no known safe exposure level to them is sufficient to sustain the standard. In the course of its opinion the court explained:

> The Secretary's decision to establish a .15 mg/m^3 exposure level . . . was a policy judgment on the basis of the best available evidence as to what the industry could achieve in an effort to best protect its coke oven employees. This decision is not a f .tual determination for which we need to find substantial evidence in the record to support. Under the Act, the Secretary's task combines elements of legislative policy determinations and fact finding. . . . In this instance his ultimate determination of the appropriate exposure level is a legislative decision in the exercise of congressionally delegated powers. [577 F.2d at 833.]

The conflict created by the decision below requires immediate resolution. There are presently pending before courts of appeals challenges to three OSHA standards involving toxic substances: inorganic arsenic (before the Ninth Circuit); cotton dust (before the District of Columbia Circuit); and lead (before the Fifth and Third Circuits). In each case the Secretary was unable to determine the precise effect of low level exposure to the particular substance and thus to make the finding required by the Fifth Circuit (but not by the other circuits) as to the extent of benefits that will result from reducing exposure to the lowest feasible level. The validity of those standards, each of which affects hundreds of workplaces and thousands of workers, thus depends upon how the question presented here is resolved.

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[18] This is the portion of *Plastics Industry* that the court below cited as contrary to its holding. *See* n. 11 *supra*.

Moreover, the standards presently under review are only the first of the standards that must be set to regulate the myriad of carcinogens in the workplace. If the Court does not settle the question presented here as to the Secretary's power to issue standards regulating carcinogens, the Secretary will be unable to get on with the congressionally mandated job of protecting the health of American workers. As matters now stand, employer organizations, by filing the first instituted review petition in the Fifth Circuit, will be able to use the decision below to defeat the Secretary's power to issue each new standard. Employers will be unable to do so, however, if the first petition is filed in the District of Columbia, Second or Third Circuits.[14] The mischief created by this situation was recently highlighted by a courthouse race which ended in a dead heat when those who thought the new standard governing occupational exposure to lead went too far filed in the Fifth Circuit while those who felt the standard did not go far enough simultaneously filed in the Third Circuit.

[14] Under § 6(f), see n. 9 *supra*, any person "adversely affected" by an OSHA standard can bring a pre-enforcement petition to review the standard in the circuit in which such person "resides or has his principal place of business." This means that every standard which impacts upon an employer in the Fifth Circuit—which is to say every OSHA standard—could be challenged before that court if employer groups arrange their filings so that the first review petition is filed by an employer in the Fifth Ciruit, and if no other aggrieved group first files for review elsewhere. (Under 28 U.S.C. § 2112(a) all challenges to an agency's orders are to be transferred to and heard by the court in which the first challenge is filed.)

II. THE DECISION BELOW INCORRECTLY DECIDES AN IMPORTANT ISSUE OF FEDERAL LAW WHICH OUGHT TO BE RESOLVED BY THIS COURT.

The court of appeals' decision requiring the Secretary before promulgating a regulation lowering the permissible exposure level for a carcinogen to estimate with some precision the number of workers who thereby would be saved from contracting cancer is inconsistent not only with the decisions of three other circuits; the court's decision is also at war with the language, history and purpose of the Act itself, as we proceed to show.

The purpose of the Act is stated in its preamble: "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources." 29 U.S.C. § 651. Of particular concern to Congress in enacting this statute was what Representative Daniels, the floor manager of the bill in the House, aptly called the "on-the-job pollution crisis"—that is, the fact that there are "millions of . . . men and women in our workforce whose lives are daily being placed in jeopardy from chemicals, insecticides, and pesticides."[15] The method Congress adopted to deal with this "crisis" was to delegate to the Secretary of Labor broad discretion to promulgate "occupational safety and health standard[s]," 29 U.S.C. § 655(b), and to impose upon employers the duty to "comply with occupational safety and health standards [thus] promulgated," *id.* § 654(a)(2).

Congress defined in express terms the substantive criteria by which the Secretary is to exercise the power delegated

[15] The Subcommittee on Labor of the Senate Committee on Public Welfare has published a compilation of the Act's legislative history entitled, *Legislative History of the Occupational Safety and Health Act of 1970*. Representative Daniels' statement appears at pp. 1002-03.

to him. Those criteria are set forth in § 6(b)(5) of the Act, 29 U.S.C. § 655(b)(5), which provides in pertinent part:

> The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection shall set the standard which *most adequately assures*, to the extent feasible, on the basis of the *best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.* [Emphasis added.]

Under § 6(b)(5) the Secretary is thus required to regulate occupational exposure to a toxic material when he concludes from the "best available evidence" that absent such regulatory action employees will suffer material impairment of health from regular exposure to the particular toxic substance. That section does not leave room for an interpretation that would render the Secretary powerless to act in such circumstances until further evidence becomes available showing how many employees will suffer health impairments. Yet that is precisely what the holding of the court below requires.

The Fifth Circuit was of the view that it was unnecessary to reconcile its holding with the substantive criteria set forth in § 6(b)(5). See App. at 15a-16a, 21a. The court apparently believed it was relieved of that burden by a subsection of the general definitional section of the Act. That subsection, § 3(8), 29 U.S.C. § 652(8), defines an "occupational safety and health standard" as a standard "which requires conditions . . . reasonably necessary or appropriate to provide safe or healthful employment and places of employment." The court below thought that without a finding as to the extent of benefits that will result from an OSHA standard, the Secretary could not "determine that [the] standard . . . is reasonably necessary."[16] But § 3(8) does

[16] The court below pointed to nothing in the legislative history of the Act or in the cases interpreting it to support the court's interpretation of § 3(8). Instead, the court relied entirely on its own decision in *Aqua Slide 'N Dive* v. *Consumer Product Safety Comm.* [*CPSC*], 569 F.2d 831 (1978). But that decision involved interpretation of a very different Act with very different language and a very different history applied to a very different problem. The question in *Aqua Slide* was whether the CPSC could require a particular label—one warning users of swimming pool slides of the danger of becoming paralyzed through improper use—without making a determination as to whether anyone was likely to heed such a warning—a determination which plainly is not on the frontiers of scientific knowledge. In holding that such a finding was required, the court relied on the peculiar language of 15 U.S.C. § 2058(c)(2)(A) which compels the CPSC, before promulgating a regulation, to find that the regulation is "reasonably necessary to eliminate or reduce *an unreasonable risk of injury*" and on the special legislative history of that section. See 569 F.2d at 839-40. Thus, whatever its merits, *Aqua Slide* sheds no light on the meaning of § 3(8).

not state that a standard must, in the abstract, be "reasonably necessary"—whatever that might mean. Rather, the Act declares that a standard must be reasonably necessary or appropriate to achieve a *particular end*. That end is the one stated in § 6(b)(5): to provide the most adequate assurance feasible that *no* employee will suffer health impairment from exposure to the substance being regulated, even if the employee's exposure is both regular and prolonged. The Secretary can determine what is reasonably necessary or appropriate to provide that assurance without a finding as to the number of employees who would otherwise actually suffer a health impairment. Thus the language of §§ 3(8) and 6(b)(5) cuts against, not for, the decision below.

Further, the interpretation of the statute just set forth, but not the Fifth Circuit's interpretation, is consistent with Congress' intent in enacting this law. The Fifth Circuit has read into the Act a requirement that would preclude the Secretary from regulating any carcinogen until he is able to resolve an issue on the "frontiers of science": the extent

to which exposure to low levels of carcinogens causes cancer (and thus the extent of the benefits that would be realized by regulating low level exposures). Yet in adopting the Act Congress expressly authorized the Secretary to act on the basis of *available* evidence and declared it "vital" that the Secretary not "be paralyzed by debate surrounding diverse medical opinions."[17] The importance of avoiding such paralysis was recently explained by Judge Tamm:

> What scientists know about the causes of cancer is how limited is their knowledge. The record in this case demonstrates that it may take decades for human exposure to result in cancer; in the meantime, the case for inferring a cancer danger with respect to an incompletely understood substance is vigorously disputed. If regulation were withheld until the danger was demonstrated conclusively, untold injury to public health could result.[18]

The court below thus was wrong in holding that the Secretary lacked sufficient information to restrict the exposure of employees to benzene to the lowest feasible level.

CONCLUSION

For all the foregoing reasons, the petition for a writ of certiorari should be granted.

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[17] H.R. Rep. No. 91-1291 at 18, in *Legislative History, supra* note 15, at 848.

[18] *Environmental Defense Fund* v. *EPA*, No. 77-1091, Slip. op. at 57-58 (D.C. Cir., Nov. 3, 1978).

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1978

Nos. 78-911 and 78-1036

INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
Petitioner,
v.
AMERICAN PETROLEUM INSTITUTE, *et al.*,
Respondents.

RAY MARSHALL, SECRETARY OF LABOR,
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v.
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On Petitions for a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

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MEMORANDUM OF THE AMERICAN IRON AND STEEL INSTITUTE IN SUPPORT OF PETITIONS FOR A WRIT OF CERTIORARI

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The American Iron and Steel Institute ("AISI") and certain individual steel company respondents [1] submit this Memorandum in Support of the Petitions for a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit which were filed in the above-styled actions by the Industrial Union Department, AFL-CIO ("IUD") and the Secretary of Labor (the "Secretary") on December 7, 1978 and December 26, 1978, in Nos. 78-911 and 78-1036, respectively. Citations to the opinion below (*American Petroleum Institute* v. *Occupational Safety and Health Administration*, 581 F.2d 493 (5th Cir. 1978)), and the regulations in question, a statement of the basis for this Court's jurisdiction, and references to the statute involved in this proceeding are set forth in the Petitions filed by IUD and the Secretary.

QUESTIONS PRESENTED

1. Whether the Secretary has unbridled discretion to adopt occupational health standards that impose enormous costs on American employers and consumers, without making (or even attempting to make) a determination that the requirements of such a standard are "reasonably necessary or appropriate to provide safe or healthful employment and places of employment."

2. Where the Secretary has made no effort whatsoever to estimate the health benefits of reducing benzene exposures from 10 parts per million ("10 ppm") to 1 ppm and has identified no evidence showing what benefits, if any, can be expected to result from such a reduction, is his conclusory determination that the expected benefits "are likely to be appreciable" supported by substantial evidence?

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[1] Bethlehem Steel Corporation, Cyclops Corporation, Jones & Laughlin Steel Corporation, National Steel Corporation, Shenango Incorporated and United States Steel Corporation.

COUNTERSTATEMENT OF THE CASE

The Occupational Safety and Health Act of 1970 (the "Act") authorizes the Secretary, acting through the Occupational Safety and Health Administration ("OSHA"), to promulgate occupational safety and health standards that are "reasonably necessary or appropriate to provide safe or healthful employment and places of employment." 29 U.S.C. §§ 652(8), 655. Recognizing that industrial health resources are not unlimited and that workplace health and safety risks cannot be eliminated entirely, Congress endorsed the objective of assuring safe and healthful working conditions "so far as possible" (29 U.S.C. § 651(b)) and placed a number of practical limitations on the Secretary's authority to adopt health standards for the regulation of toxic substances. Not only must such standards (like all standards under the Act) be "reasonably necessary" to protect worker health; they also must be based upon the "best available evidence"—including the "latest available scientific data" and "experience gained under . . . other health and safety laws"—and, in all cases, must be "feasible." 29 U.S.C. § 655(b)(5).

Benzene is a toxic material to which the foregoing statutory provisions are applicable. It is a "ubiquitous hydrocarbon compound" (581 F.2d at 497, App. A at 5a) [2] that is naturally present in water supplies, animal and plant matter and many foods, and that may be found in the ambient air at background levels approaching 0.5 ppm.[3] Approximately 94% of the benzene pro-

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[2] "App." references are to the Appendix submitted by Petitioner IUD in No. 78-911. References to the administrative record are abbreviated as "Tr." for the Transcript and "Ex." for Exhibits.

[3] *See, e.g.*, Testimony of Dr. Herman F. Kraybill (National Cancer Institute), Ex. 84B-18, App. A at 2-3, Tr. 1176, 1192-94; Testimony of Edward Baier (NIOSH), Ex. 84A at 7, Tr. 749-50, 1132;

duced in the United States is derived from the refining of crude oil, and approximately 6% is produced as a by-product of the coking process in the steel industry. 581 F.2d at 497-98, App. A at 6a. Among its many uses, benzene serves as an octane-boosting component in gasoline production, as a petrochemical feedstock and as an industrial solvent; it also has a wide range of other industrial applications. *Id.*

Since the turn of the century, it has been recognized that benzene exposures at sufficiently high concentration levels are capable of producing acute and chronic non-malignant effects in humans. 581 F.2d at 498, App. A at 6a-7a. Because of its toxicity, benzene exposures have been regulated by various states and standard-setting organizations for several decades. *Id.* In 1971, pursuant to 29 U.S.C. § 655(a), OSHA adopted the 10 ppm threshold limit value of the American National Standards Institute (a national consensus standard) as an effective OSHA standard for benzene. *Id.* That standard (of 10 ppm as an eight-hour time-weighted average limit [4]) was codified at 29 C.F.R. § 1910.1000 Table Z-2 (1977) and is presently in effect.

During the 1970s, several investigators reported findings tending to confirm earlier indications of an association between chronic exposure to high benzene concentrations (in the hundreds of ppm) and an increased incidence of leukemia. For example, Dr. Muzaffer Aksoy, a witness upon whom OSHA relied heavily, reported

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Mobil Research and Development Corp. Memorandum, Ex. 117 at 1-2; Memorandum of Nelson A. Leidel (NIOSH), Ex. 95 at 2, 4; July 12, 1977 letter from Charles Custard, Director, HEW Office of Environmental Affairs, Ex. 205A at 2.

[4] This means that a worker will not be exposed to more than 10 parts benzene per million parts of air as a time-weighted average over the course of an eight-hour working day.

leukemia cases among workers employed in unhygienic and poorly ventilated Turkish shoe shops where benzene exposures ranged from 150-650 ppm.[5]

The studies of Dr. Aksoy and others,[6] which showed that benzene exposures in excess of 100 ppm could increase the risk of developing leukemia, were known to OSHA and various scientific bodies prior to 1977. Yet this evidence associating high level (100 ppm and above) benzene exposures with leukemia did not persuade prestigious scientific bodies such as the National Research Council and the International Workshop on the Toxicology of Benzene that the 10 ppm standard was inadequate to protect worker health.[7] Indeed, during 1976, OSHA itself refused two requests to reduce the exposure limit from 10 ppm to 1 ppm.[8]

What suddenly induced OSHA to order an immediate reduction in permissible benzene exposures from 10 ppm to 1 ppm was an April 1977 report (the so-called "Infante Study" [9]) that OSHA initially characterized as demonstrating that leukemia had been induced in workers exposed to benzene levels "significantly below . . . 10 ppm." [10] Largely on the basis of the Infante Study,

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[5] Ex. 60 at 45; Tr. 157, 185.

[6] *E.g.*, Dr. Enrico Vigliani, who reported leukemia cases among workers in Italy. Ex. 2-27.

[7] National Research Council, Committee on Toxicology, *A Review: Health Effects of Benzene* ii (June 1976) (Ex. 2-4); International Workshop on the Toxicology of Benzene, Final Report 7 (November 9-11, 1976), (Ex. 17).

[8] These requests were made by the United Rubber Workers (Ex. 2-42) and the National Institute for Occupational Safety and Health ("NIOSH") (Ex. 2-6).

[9] P. Infante, *et al.*, "Leukemia Among Workers Exposed to Benzene" (April 28, 1977), Ex. 40.

[10] OSHA Opposition to Stay Pending Judicial Review of the ETS, *American Petroleum Institute* v. *OSHA*, No. 77-1973 (5th Cir.) (filed June 1, 1977).

OSHA, on May 3, 1977, issued an emergency temporary standard ("ETS") for benzene, reducing the permissible exposure limit to 1 ppm,[11] and proposed a permanent standard having a comparable limitation.[12] The ETS was stayed by the Fifth Circuit and never took effect. 581 F.2d at 499, App. A at 9a.

At the hearings on the proposed permanent standard in July and August 1977, the Infante Study was subjected to withering criticism directed to both its methodology and interpretation.[13] But even when the methodological and interpretative flaws are overlooked, it was made crystal clear that the workers studied by Dr. Infante were exposed to benzene concentrations that probably averaged 100 ppm or more, with occasional exposure levels of several hundred parts per million. 581 F.2d at 498-99 n.13, App. A at 8a n.13. And one of the authors of the Infante Study observed that anyone who interpreted the study (as OSHA had) to demonstrate that benzene exposures "generally below 25 ppm have already induced leukemia" would be going "off the deep end . . . ." [14]

In short, once OSHA's initial misperception of the Infante Study was corrected, it became clear that the study—which had galvanized OSHA into such precipitous action—added virtually nothing to what had been reported earlier. No one had yet come forward with evidence associating benzene exposures below 100 ppm (let

[11] 42 Fed. Reg. 22516 (May 3, 1977).

[12] 42 Fed. Reg. 27452 (May 27, 1977).

[13] The nature and substance of this criticism is discussed at pages 31-35 of the Post-Hearing Brief submitted by AISI (Ex. 217-36) and at pages 22-46 of the Post-Hearing Brief submitted by the American Petroleum Institute ("API") (Ex. 217-33).

[14] Testimony of Ronald Young, Tr. 815-816. Dr. Infante and Edward J. Baier, Deputy Director of NIOSH, also rejected any such interpretation of the study. Tr. 1137-1140.

alone below 10 ppm) with leukemia, and no one has done so to date. To the contrary, a considerable body of evidence in the record suggested that benzene exposures of 10 ppm presented no leukemia risk whatsoever.[15]

But, even conceding the possibility that benzene exposures of 10 ppm may present some risk of leukemia, the fact is that OSHA identified no evidence establishing what that risk might be and made no effort whatsoever to acquire such evidence or to estimate the extent to which the risk would be reduced if the exposure limit were lowered from 10 ppm to 1 ppm. Instead, OSHA's spokesman at the hearing stated that he could not estimate what incremental benefit or added protection, if any, would be realized by reducing the permissible exposure level.[16] And no attempt was made by the agency to fill this gap in its knowledge.

The final standard, reducing permissible exposures from 10 ppm to 1 ppm, was adopted on February 3, 1978.[17] OSHA justified the required reduction to 1 ppm on the basis of its determinations that high level benzene exposures have been shown to cause leukemia and

[15] Expert testimony pointed to biochemical and physiological evidence of a threshold level for benzene-related leukemia well in excess of 10 ppm, and the record contained references to a large number of studies providing empirical evidence that low level benzene exposures have not been associated with an excess of leukemia. In addition, it was shown that the leukemia cases disappeared entirely when the benzene levels of 100 ppm and above were lowered —though not eliminated—in the industrial populations studied by Drs. Infante, Aksoy and Vigliani, whose reports of an excess incidence of leukemia among workers exposed to high benzene concentrations served as the principal basis for OSHA's determination to reduce the exposure limit from 10 ppm to 1 ppm. This evidence is discussed in the AISI Post-Hearing Brief (Ex. 217-36) at 51-71, and in the API Post-Hearing Brief (Ex. 217-33) at 61-91.

[16] Testimony of Grover C. Wrenn, OSHA's Deputy Director of Health Standards, Tr. 96-97, 130-131.

[17] 43 Fed. Reg. 5918 (February 10, 1978), App. C.

that, while scientific opinion is divided on the question, there is substantial evidence indicating that no absolutely safe level for benzene exposure is presently known.[18] Having made those two determinations, OSHA simply assumed that reducing permissible exposures from 10 ppm to 1 ppm would produce "appreciable benefits" [19] and established 1 ppm as the lowest level that was technologically feasible and that "would not threaten the financial welfare of the affected firms or the general economy." [20]

OSHA acknowledged that various participants in the proceeding (including the President's Council on Wage and Price Stability) had urged it to "estimate the incremental reduction in health risks which are associated with the reduction in employee exposure to benzene." [21] However, OSHA took the position that the Act precludes it from undertaking to estimate the benefits (in terms of reduced risk) that are expected to result from a reduction in the permissible exposure limit and from evaluating those benefits in light of the costs involved.[22] Nevertheless, OSHA blithely asserted that the "benefits of the proposed standard are likely to be appreciable," even though it did not identify or analyze any record evidence that would support such a determination.[23]

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[18] *See* 43 Fed. Reg. 5931-32 (Feb. 10, 1978), App. C at 122a-125a; 581 F.2d at 501, App. A at 13a.

[19] 43 Fed. Reg. 5941 (Feb. 10, 1978), App. C at 162a.

[20] 581 F.2d at 503, App. A at 17a.

[21] 43 Fed. Reg. 5940-41 (Feb. 10, 1978), App. C at 160a-161a.

[22] 43 Fed. Reg. 5941 (Feb. 10, 1978), App. C at 162a. In his Petition for a Writ of Certiorari in No. 78-1036, the Secretary stresses "that this case presents the issue whether Section 655(b) prohibits the balancing of costs and benefits for toxic substances." Petition of the Secretary at 17 n.10.

[23] 43 Fed. Reg. 5941 (Feb. 10, 1978), App. C at 162a.

Petitions for review of the final benzene standard were promptly filed by various parties, including AISI, and consolidated for consideration by the Fifth Circuit. In its argument to the court below, OSHA advanced two principal contentions in support of the standard. First, OSHA asserted that the statutory requirement that occupational health and safety standards must be "reasonably necessary or appropriate to provide safe or healthful employment and places of employment," 29 U.S.C. § 652(8), should be read out of the Act entirely for a substance like benzene. 581 F.2d at 501, App. A at 14a. Second, OSHA claimed that, even if the "reasonably necessary" criterion did apply, it was satisfied by the agency's mere assumption that the benefits of reducing the permissible exposure limit from 10 ppm to 1 ppm are likely to be appreciable. 581 F.2d at 502-503, App. A at 15a-18a. In short, OSHA urged the court below to follow the same course taken by the Third Circuit in upholding the Coke Oven Emissions Standard in *American Iron and Steel Institute* v. *OSHA*, 577 F.2d 825 (1978).[24]

The court below rejected both of these contentions. It declined "to read [the] words [of Section 3(8)] out of the OSHA legislation," holding that "[i]f a standard does not fit this definition, it is not one that OSHA is authorized to enact." 581 F.2d at 502, App. A at 15a. OSHA's position, the court observed, would give the agency "unbridled discretion to adopt standards designed

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[24] Two petitions seeking review of the *Coke Oven Emissions* case, one filed by AISI (No. 78-919) and the other by Republic Steel Corporation (No. 78-918), are pending before this Court. The petitions filed by the Secretary and IUD seeking review of the Fifth Circuit's *Benzene* decision both assert that that decision conflicts with the decision of the Third Circuit in the *Coke Oven Emissions* case. *See* Secretary of Labor's Petition for a Writ of Certiorari in No. 78-1036 at 12-14; IUD's Petition for a Writ of Certiorari in No. 78-911 at 12, 15. As discussed at pages 11-13 below, AISI agrees with this position and urges that certiorari be granted in both cases to resolve the conflict.

to create absolutely risk-free workplaces regardless of cost." 581 F.2d at 502, App. A at 15a. Such a position, the court held, was inconsistent both with the "reasonably necessary" requirement of Section 3(8) and with the "pragmatic limitations" set forth in Section 6(b)(5) of the Act. 581 F.2d at 502, App. A at 16a. Rather, those statutory provisions require OSHA to estimate the expected benefits of its standard and to determine whether those benefits "bear a reasonable relationship to the costs imposed by the standard." 581 F.2d at 503, App. A at 17a.

In the court's view, this obligation to consider the standard's expected benefits in light of the costs imposed was not satisfied by OSHA's conclusory assumption that the benefits of reducing permissible exposures from 10 ppm to 1 ppm are likely to be appreciable. The court noted that OSHA was "unable to point to any studies or projections supporting such a finding." 518 F.2d at 503, App. A at 18a. Moreover, the court pointed out that, despite the fact that risk assessments are commonly made by other federal agencies and that such estimates could be (and, in fact, had been) performed for benzene, OSHA made no effort whatsoever to perform such an analysis of the proposed standard, 581 F.2d at 504 n.23, App. A at 19a n.23.

In short, the court found that OSHA's conclusory statement that appreciable benefits are likely to result from reducing the permissible exposure limit to 1 ppm was based upon assumption and sheer speculation. Particularly since "OSHA [was] unable to point to any empirical evidence documenting a leukemia risk at 10 ppm even though that has been the permissible exposure limit since 1971," the court concluded that the agency's finding of appreciable benefits was not supported by substantial evidence as required by Section 6(f) of the Act, 29 U.S.C. § 655(f). 581 F.2d at 503, App. A at 18a. "Congress," the court stated, "intended for OSHA to regulate on the basis of

more knowledge and fewer assumptions than this record reflects." 581 F.2d at 505, App. A at 21a.

REASONS FOR GRANTING THE WRIT

Although AISI was a successful petitioner below and submits that the Fifth Circuit's decision was plainly correct, AISI nevertheless believes that certiorari should be granted in this case as well as in the *Coke Oven Emissions* case because of the conflict between the decisions of the Fifth and Third Circuits and the importance of the issues in conflict.

As indicated above, OSHA's determination to reduce the permissible exposure limit for benzene to 1 ppm was based upon its findings (1) that benzene exposures have been found to cause leukemia, (2) that no absolutely safe level of exposure to benzene is presently known, and (3) that a 1 ppm exposure limit is technologically feasible and within the financial capability of the affected industries. OSHA's determination to reduce the permissible exposure level for coke oven emissions to .15 mg/m^3 was, *mutatis mutandi*, based upon precisely the same three findings—*i.e.*, (1) that exposures to coke oven emissions have been found to cause cancer, (2) that no absolutely safe level of exposure to coke oven emissions is presently known, and (3) that compliance with a .15 mg/m^3 exposure limit is within the technological and financial capability of the coking industry.[25]

In reviewing the Benzene Standard, the Fifth Circuit held that this approach to standard setting does not satisfy the requirements of the Act. Yet in reviewing the Coke Oven Emissions Standard,[26] the Third Circuit held precisely the contrary, stating that the

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[25] *See* 41 Fed. Reg. 46742-46751 (October 22, 1976).

[26] 29 C.F.R. § 1910.1029 (1977).

validity of the standard was established by OSHA's showing that coke oven emissions are a carcinogen for which no absolutely safe level of exposure is known and that the required reduction in the permissible exposure limit is technologically feasible and can be implemented financially without causing "massive dislocation" in the industry.[27]

Moreover, in contrast to the Fifth Circuit's requirement that the mandated reduction in the permissible exposure limit must be supported by substantial evidence, the Third Circuit treated OSHA's determination to establish a 0.15 mg/m³ exposure level as "a policy judgment . . . not a factual determination for which we need to find substantial evidence in the record to support." [28] As pointed out at pages 12 and 15 of IUD's Petition for a Writ of Certiorari in No. 78-911, this holding of the Third Circuit in the *Coke Oven Emissions* case directly conflicts with the Fifth Circuit's decision in the *Benzene* case. And it is precisely this issue—*i.e.*, whether there must be substantial evidence to support OSHA's determination of .15 mg/m³ as the permissible exposure limit for coke oven emissions—that constitutes the most critical element of AISI's Petition in No. 78-919 to review the *Coke Oven Emissions* decision.

Like the Secretary and IUD,[29] we believe that, despite their separate factual records, the decisions of the Third and Fifth Circuits are in conflict, as we stated in our petition for review of the *Coke Oven Emissions* case (No. 78-919). That the two opinions reflect a difference in reasoning and in the approach to be applied in reviewing occupational health standards for toxic substances can

[27] *American Iron and Steel Institute* v. *OSHA*, 577 F.2d 825, 836 (3d Cir. 1978).

[28] *Id.* at 833.

[29] Secretary of Labor's Petition for a Writ of Certiorari in No. 78-1036 at 12-14; IUD's Petition for a Writ of Certiorari in No. 78-911 at 12, 15.

scarcely be denied. Nor is there room to doubt that the cases present important questions of federal law that have an enormous impact on the nation's economy.

While we differ from the Secretary and IUD on the question of which court properly interpreted and applied the relevant provisions of the Act, we agree that the two opinions cannot fairly be reconciled and submit that this Court should grant certiorari to review both decisions and remove the uncertainty currently surrounding these critical issues of proper statutory interpretation and judicial function in the review of OSHA standards.

CONCLUSION

For the reasons set forth above, AISI agrees with the Secretary and IUD that a writ of certiorari should be issued to review the judgment of the Fifth Circuit in the instant *Benzene* case. And we emphasize that, by parity of reasoning, certiorari should also be granted to review the Third Circuit's *Coke Oven Emissions* decision, as urged in our petition in No. 78-919.

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v.

AMERICAN PETROLEUM INSTITUTE, *ET AL.*,
Respondents.

ON PETITIONS FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

RESPONSE OF REPUBLIC STEEL CORPORATION

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January 26, 1979

IN THE

Supreme Court of the United States

OCTOBER TERM, 1978

Nos. 78-911 and 78-1036

INDUSTRIAL UNION DEPARTMENT, AFL-CIO,

Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, ET AL.,

Respondents.

RAY MARSHALL, SECRETARY OF LABOR,

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RESPONSE OF REPUBLIC STEEL CORPORATION

Republic Steel Corporation ("Republic") submits this response to the Petitions for a Writ of Certiorari filed by the Industrial Union Department, AFL-CIO ("IUD") and the Secretary of Labor seeking review of the Fifth Circuit's decision in *American Petroleum Institute* v. *OSHA*, 581 F.2d 493 (5th Cir. 1978). These petitions were filed on December 7, 1978 and December 26, 1978, in Nos. 78-911

and 78-1036, respectively. On December 29, 1978, all non-Government respondents requested an extension of time to permit simultaneous response to these petitions. On January 2, 1979 the time for responding was extended to January 26, 1979.

The decision below is set forth at pages 1a to 33a of the Appendix filed by IUD.[1] The basis for this Court's jurisdiction and the statutes and regulations involved are set forth in the petitions filed by IUD and the Secretary of Labor.

Questions Presented

The questions presented concern the development of an occupational health standard by the Occupational Safety and Health Administration ("OSHA"). An occupational health standard is defined at 29 USC 652 (8). It is required by statute to be feasible, 29 USC 655(b)(5); and considerations of feasibility are recognized to involve both economics and technology. The standard in question regulates exposure to benzene ("the benzene standard"). Part of the benzene standard sets a maximum permissible exposure limit to benzene.

1. Whether OSHA is required to weigh the costs and benefits of an occupational health standard in order to establish its economic feasibility under 29 USC 655(b)(5)?

2. Whether the standard of review of the feasibility of a permissible exposure limit promulgated under 29 USC 655(b)(5) is substantial evidence in the record considered as a whole?

These same questions are presented by Republic in a Petition for a Writ of Certiorari, No. 78-918, to review the opinion and judgment of the United States Court of Appeals for the Third Circuit in *American Iron and Steel*

[1] This Appendix will be referred to in the form "App. at ——a".

Institute, et al. v. *OSHA*, 577 F.2d 825 (3d Cir. 1978). That petition concerns an occupational health standard for exposure to coke oven emissions.

Counterstatement of the Case

Benzene is a naturally occurring substance found in crude oil, vegetable and animal matter, and the air we breathe. Concentrations of benzene in the ambient air—removed from any man-made source of benzene—have been observed to approach 0.5 parts of benzene per million parts of air ("0.5 ppm").[2]

Benzene is widely used as a petrochemical feed stock, as a solvent, and as an octane booster for gasoline. At one time benzene was primarily produced as a by-product of the coking process in steel mills. While the petrochemical and petroleum refining industries have supplanted the steel industry as the major source of benzene, significant amounts of benzene are still made as a by-product of the coking process.

Because benzene is recognized as a toxic material, exposure to benzene has been controlled under Section 6 of the Occupational Safety and Health Act of 1970. 29 USC 655. Initially, OSHA adopted a permissible exposure limit for benzene that was 10 ppm. However, in April 1977, in a document which came to be called the Infante Report, excess leukemia was reported among workers who were believed to have been exposed to low levels of benzene during the 1940s. OSHA interpreted this Report as demonstrating that leukemia had been found in workers exposed to benzene concentrations "significantly below

[2] *E.g.*, Testimony of Dr. Herman Kraybill of National Cancer Institute, Hearing Exhibit 84B-18, App. A at 2-3, Tr. 1176, 1192-94; Testimony of Edward Baier of National Institute of Occupational Safety and Health, Hearing Exhibit 84A at 7, Tr. 749-50, 1132.

. . . 10 ppm. . . ." OSHA Opposition to Stay Pending Judicial Review, at 9-10, filed June 1, 1977 in *American Petroleum Institute* v. *OSHA* (5th Cir., No. 77—1973). Relying on the Infante Report, OSHA issued an emergency temporary standard for benzene which reduced the permissible exposure limit from 10 ppm to 1 ppm. 42 Fed. Reg. 22516 (May 3, 1977). OSHA also proposed a permanent standard requiring the same reduction in permissible exposure limit. 42 Fed. Reg. 27452 (May 27, 1977). The temporary standard was stayed by the Fifth Circuit and never took effect.

At the administrative hearings held on the proposed permanent standard, OSHA's reliance on the Infante Report was discovered to be misplaced. As the Court below stated, the employees studied by Infante were actually exposed to benzene levels "around 100 ppm during most of the period studied with occasional exposure levels as high as several hundred parts per million." 581 F.2d at 498, n. 13; App. at 8a, n. 13. Moreover, the authors of the Infante Report repudiated the use to which OSHA had put the study. One of the authors expressly warned that anyone who used the Report to demonstrate that benzene exposures below 25 ppm had induced leukemia would be going "off the deep end. . . ." Testimony of Ronald Young, Tr. 815-816.

Nevertheless, on February 3, 1978, OSHA promulgated a permanent benzene standard in which the permissible exposure limit was reduced from 10 ppm to 1 ppm. 43 Fed. Reg. 5918 (February 10, 1978); App. at 34a-251a. OSHA justified this reduction on the following reasoning: benzene is a human carcinogen, there is no safe level of exposure to a human carcinogen, under these circumstances it is necessary for the permissible exposure to benzene to be the lowest level feasible, and 1 ppm is the lowest feasible level. 43 Fed. Reg. 5931, 5932, 5947; App. at 122a, 124a-125a, 187a. OSHA made no attempt to identify the

benefits that would be produced by such a reduction, merely asserting that the benefits were "likely to be appreciable" and that OSHA was "not obligated to carry out further exercises toward more precise calculations of benefit . . ." 43 Fed. Reg. 5941; App. at 162a-163a.

Petitions for judicial review of the benzene standard were promptly filed in the Fifth Circuit. Before the Court below, OSHA argued that it had no obligation to justify the costs of compliance with its standard in terms of the benefits received. OSHA further argued that its estimate of costs and its assumption that the benefits of the reduction "may be appreciable" were sufficient to supply any justification that might be needed. 581 F.2d at 501-503; App. at 14a-18a.

The Court below rejected both arguments. In view of the definition of an occupational health standard found in 29 USC 652(8), and the requirements for such standards established in 29 USC 655(b)(5), the Court held that OSHA did not have "unbridled discretion to adopt standards designed to create absolutely risk-free workplaces regardless of cost." 581 F.2d at 502; App. at 15a. OSHA was required "to determine whether the benefits expected from the standard bear a reasonable relationship to the costs imposed by the standard." 581 F.2d at 503; App. at 17a.

The Court then found that OSHA had not demonstrated such a reasonable relationship. Although the costs of the benzene standard were adequately known, OSHA had not determined its benefits, choosing instead to rely on the assumption that the benefits "may be appreciable". 581 F.2d at 503-505; App. at 17a-21a. Since there was no way to establish a reasonable relationship between costs and benefits without information on the benefits, the Court set the benzene standard aside.

Reasons for Granting the Writ

Also pending before this Court are two petitions for certiorari relating to an occupational health standard for exposure to coke oven emissions, Republic's petition No. 78-918 and that of the American Iron and Steel Institute, No. 78-919. The issues involved in the two benzene petitions and the two coke oven petitions are similar because OSHA used the same reasoning process to develop the permissible exposure limit for benzene that it used in developing the permissible exposure limit for coke oven emissions. In both cases OSHA determined that the substance to be regulated was a carcinogen. It then determined that there was no safe level of exposure to a carcinogen; and made the judgment that exposure to a carcinogen should be reduced to the lowest level feasible. Finally, OSHA set what it believed was the lowest feasible level, concluding that it was one part per million for benzene and 0.15 milligrams of the benzene soluble fraction of total particulate matter per cubic meter of air ("0.15 mg/m^3 BSFTPM") for coke oven emissions.

The feasibility of the permissible exposure limit and the health standard itself was challenged both in the benzene case and in the coke oven case. Feasibility involves both economic and technological considerations.[3] In the benzene case, petitioners' challenge was directed to the reasonableness of the costs of the standard in relation to its alleged benefits. In the coke oven case, Republic challenged both the economic and technological feasibility of the coke oven standard. In the benzene case, the Fifth Circuit found that OSHA was required to determine whether the benefits of the standard bore a "reasonable relationship" to its costs and, in the absence of substantial evidence of benefits,

[3] ". . . the Secretary has consistently established standards requiring the lowest level of exposure that can be achieved within the bounds of economic and technological feasibility." Secretary of Labor's petition for certiorari in No. 78-1036, at 12.

was compelled to set the standard aside. In the coke oven case, however, in order to determine economic feasibility, the Third Circuit looked solely at industry's ability to bear the cost of the standard and, upon finding that the standard would not cause "massive economic dislocation", held the standard to be economically feasible. 577 F.2d at 835-837. With respect to technological feasibility, the Third Circuit found that OSHA's decision to establish the 0.15 mg/m^3 BSFTPM exposure limit was a policy judgment and therefore immune from review on the basis of substantial evidence. 577 F.2d at 833.

As noted at page 13 of the Secretary of Labor's petition for certiorari, these two decisions conflict not only in result but also in reasoning. To reach the economic test of "reasonable relationship", the Fifth Circuit explicitly rejected OSHA's argument that it was enough to establish that the benzene standard did not "threaten the financial welfare of the affected firms." 581 F.2d at 503; App. at 17a. To hold that the feasibility of the permissible exposure limit was a matter of policy, the Third Circuit explicitly rejected Republic's argument that feasibility was a factual issue subject to judicial review on the basis of substantial evidence in the record. 577 F.2d at 833.

The economic resources of industry are limited. Under such circumstances, some means must be found for allocating available resources on the basis of health need. To do this, at least a rough estimate of the health need (*i.e.*, the benefits to be derived from the regulation) is necessary. For these reasons, Republic believes the Fifth Circuit was correct in insisting that OSHA quantify the benefits to be derived from the benzene standard. Moreover, because the Occupational Safety and Health Act explicitly requires that judicial review be based on substantial evidence in the record, 29 USC 655(f), Republic believes the Fifth Circuit was correct in requiring substantial evidence to support OSHA's conclusions with respect to the feasibility of the benzene standard.

Conclusion

We do not agree with the contentions of the Secretary of Labor and IUD that the Fifth Circuit erred in remanding the benzene standard. However, we do agree that the decisions of the Fifth Circuit and the Third Circuit conflict. Accordingly, we believe this Court should grant certiorari to review both decisions and to resolve these important issues.

Respectfully submitted,

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IN THE

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OCTOBER TERM, 1978

No. 78-911

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INDUSTRIAL UNION DEPARTMENT, AFL-CIO, *Petitioner*,

v.

AMERICAN PETROLEUM INSTITUTE, CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION, MANUFACTURING CHEMISTS ASSOCIATION, NATIONAL PETROLEUM REFINERS ASSOCIATION, AMERICAN PETROFINA INCORPORATED, ATLANTIC RICHFIELD COMPANY, CITIES SERVICE COMPANY, CONTINENTAL OIL COMPANY, DELTA OIL COMPANY, EXXON CORPORATION, GULF OIL COMPANY, MARATHON OIL COMPANY, PHILLIPS PETROLEUM COMPANY, SHELL OIL COMPANY, SOUTH HAMPTON OIL COMPANY, STANDARD OIL COMPANY (INDIANA), STANDARD OIL COMPANY OF OHIO, SUN OIL COMPANY OF PENNSYLVANIA, SUN OIL COMPANY OF DELAWARE, TEXACO INC., UNION OIL COMPANY OF CALIFORNIA
RUBBER MANUFACTURERS ASSOCIATION, INC., FIRESTONE TIRE & RUBBER COMPANY, GENERAL TIRE & RUBBER COMPANY, B. F. GOODRICH COMPANY, GOODYEAR TIRE & RUBBER COMPANY
E. I. DU PONT DE NEMOURS AND COMPANY
ARMSTRONG RUBBER COMPANY AND UNIROYAL COMPANY
INDEPENDENT PETROLEUM ASSOCIATION OF AMERICA
AMERICAN IRON AND STEEL INSTITUTE, BETHLEHEM STEEL CORPORATION, CYCLOPS CORPORATION, JONES AND LAUGHLIN STEEL CORPORATION, NATIONAL STEEL CORPORATION, REPUBLIC STEEL CORPORATION, SHENANGO INCORPORATED, UNITED STATES STEEL CORPORATION
AND
OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION,

Respondents.

APPENDIX TO THE PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

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APPENDIX A

THE AMERICAN PETROLEUM INSTITUTE ET AL., *Petitioners*,

THE MANUFACTURING CHEMISTS ASSOCIATION AND THE CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION, *Intervenors*,

v.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION ET AL., *Respondents*,

INDUSTRIAL UNION DEPARTMENT, AFL-CIO, *Intervenor*.

Nos. 78-1253, 78-1257, 78-1486, 78-1676, 78-1677, 78-1707 and 78-1745.

United States Court of Appeals, Fifth Circuit.

Oct. 5, 1978.

On Petitions for Review of an Order of the Occupational Safety and Health Administration.

Before COLEMAN, CLARK, and TJOFLAT, Circuit Judges.

CHARLES CLARK, Circuit Judge:

This case presents consolidated petitions for review[1] of

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[1] The petitioning or intervening producers of benzene and benzene-containing products are the American Petroleum Institute on behalf of itself and member companies; the American Iron and Steel Institute on behalf of itself and member companies; the Independent Petroleum Association of America on behalf of itself and member companies; and the Manufacturing Chemists Association on behalf of itself and member companies. The petitioning or intervening users of benzene and benzene-containing products are the Rubber Manufacturers Association on behalf of itself and member companies; the Armstrong Rubber Company and Uniroyal, Inc.; E. I. du Pont de Nemours and Company; and the Chemical Specialties Manufacturers Association on behalf of itself and member companies. The grouping of the petitioners into the producer or user category was made in order to coordinate the briefing and arguing of this case, and this opinion will continue to refer to those categories.

a new health standard limiting occupational exposure to benzene[2] promulgated by the Occupational Safety and Health Administration of the Department of Labor (OSHA), pursuant to the Occupational Safety and Health Act, 29 U.S.C.A. § 651 *et seq.* (1975) (the Act). The basis for the standard is OSHA's determination that benzene is a carcinogen for which there is no known safe level of exposure. Briefly, the standard requires employers to assure that no employee is exposed to an airborne concentration of benzene in excess of one part benzene per million parts of air (1 ppm) averaged over an eight-hour day,[3] it requires employers to assure that no employee is exposed to dermal contact with liquid benzene,[4] and it requires employers to assure that caution labels are affixed to all containers of products containing benzene and that the labels remain affixed when the product leaves the employer's workplace.[5] In addition, the standard imposes numerous compliance requirements for "each place of employment where benzene is produced, reacted, released, packaged, repackaged, stored,

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[2] The standard, to be codified at 29 C.F.R. § 1910.1028, and OSHA's statement of reasons in support of the standard are published at 43 Fed. Reg. 5918-70 (1978).

[3] The ceiling limit is 5 ppm as averaged over any fifteen minute period.

[4] OSHA promulgated an amended standard the day before oral argument of this case which exempted from the scope of the standard all work operations where the only exposure to liquid benzene or its vapors is from liquid mixtures containing 0.5 percent (0.1 percent after June 27, 1981) or less of benzene by volume. 43 Fed. Reg. 27,962-71 (1978). The original standard's absolute prohibition of dermal contact with any liquid containing any amount of benzene is therefore no longer in existence. The effect of this amendment on the issues in this case will be discussed *infra*.

[5] Not only does the scope of the amended standard affect the labeling requirement, but the amended standard also exempts from the labeling requirement liquid mixtures containing 5.0 percent or less benzene by volume which were packaged before June 27, 1978.

transported, handled, or used," with certain exceptions. These requirements include initial and continual exposure monitoring, engineering and work practice controls to reduce and maintain exposure below the permissible level, respiratory protection to prevent excessive exposure in limited situations, protective clothing and equipment to prevent dermal contact with liquid benzene, initial and continual medical surveillance, employee training programs, and retention of records regarding exposure monitoring and medical surveillance.

The petitioning producers and users of benzene and benzene-containing products principally attack the reduction of the permissible exposure limit to 1 ppm,[6] the prohibition of dermal contact with liquids containing benzene, and the labeling requirements for such liquids. The petitioners also attack several of the ancillary provisions of the standard, including its broad scope, the monitoring and medical surveillance requirements, and the specification of mandatory engineering and work practice controls.

I.

The Act authorizes the Secretary of Labor[7] to promulgate occupational safety and health standards. 29 U.S.C.A. § 655. An "occupational safety and health standard" is defined as "a standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment" 29 U.S.C.A. § 652(8). In promulgating standards

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[6] Presently the permissible exposure limit for benzene is 10 ppm. 29 C.F.R. § 1910.1000 Table Z-2 (1977). This standard has been in existence since 1971.

[7] This authority has been delegated to the Assistant Secretary of Labor for Occupational Safety and Health, the chief executive officer of OSHA. References to the Secretary and OSHA are used interchangeably in this opinion.

dealing with toxic materials, such as benzene, the Secretary is required to

> set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired.

29 U.S.C.A. § 655(b)(5). When necessary or appropriate, standards may prescribe labels or other forms of warning, protective equipment, control or technological procedures, exposure monitoring, and medical examinations. 29 U.S.C.A. § 655(b)(7).

Judicial review of occupational safety and health standards is authorized by 29 U.S.C.A. § 655(f), and on review "[t]he determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole." Several courts, including this one, have pointed out the problems involved in attempting to apply the traditional substantial evidence test in assessing OSHA standards resulting from informal rulemaking. *E.g., Associated Industries of New York State, Inc.* v. *United States Department of Labor,* 487 F.2d 342, 347-50 (2d Cir. 1973); *Florida Peach Growers Association, Inc.* v. *United States Department of Labor,* 489 F.2d 120, 127-29 (5th Cir. 1974); *Industrial Union Department, AFL-CIO* v. *Hodgson,* 162 U.S.App.D.C. 331, 336-340, 499 F.2d 467, 472-76 (1974); *Synthetic Organic Chemical Manufacturers Association* v. *Brennan,* 503 F.2d 1155, 1158-60 (3d Cir. 1974). The problem centers not on how to apply the test to factual findings subject to evidentiary development, but rather on how to review legislative-like policy judgments. With respect to the former, the substantial evidence standard provided in the statute clearly is applicable. *See, e.g., Industrial Union Department, AFL-CIO* v. *Hodgson, supra,* 499 F.2d at 474; *American Iron & Steel Institute, et al.* v. *OSHA,* 577 F.2d 825, No. 76-2358 *et al.* (3d Cir., filed March 28, 1978). Policy choices, though not so susceptible to verification or refutation by the record, must be scrutinized nevertheless. *See Associated Industries of New York, Inc.* v. *United States Department of Labor, supra,* 487 F.2d at 348. Although the courts have differed in their articulation of the standard of review of these policy judgments, they have required the Secretary's action to be consistent with the statutory language and purpose. *Synthetic Organic Chemical Manufacturers Association* v. *Brennan, supra,* 503 F.2d at 1159. As this court stated in assessing an emergency temporary standard in *Florida Peach Growers,* "it seems clear that even with the required substantial evidence test, our review basically must determine whether the Secretary carried out his essentially legislative task in a manner reasonable under the state of the record before him." 489 F.2d at 129. This includes, of course, a review of whether the Secretary exercised his decisionmaking power within the limits imposed by Congress.

II.

Benzene is a ubiquitous hydrocarbon compound (C_6H_6) that is manufactured for a wide variety of industrial uses.[8]

[8] Although benzene does occur naturally in small quantities (a few parts per billion) in certain substances, including the ambient

The petro-chemical and petroleum refining industries are responsible for 94 percent of the total domestic production of benzene, and the steel industry produces the remaining 6 percent primarily as a by-product of the coking process. The primary use of benzene is as a feedstock in the manufacture of other organic chemicals; it is also used in the manufacture of detergents, pesticides, solvents, and paint, and as a solvent and reactant in chemical laboratories. Industries currently using benzene include the chemical, printing, lithograph, rubber cements, rubber fabricating,[9] paint, varnish, stain removers, adhesives, and petroleum industries. Among the products that contain benzene are motor fuels such as gasoline, which contain up to 2 percent benzene.

Benzene has been recognized since 1900 as a toxic substance capable of producing acute and chronic nonmalignant effects in humans. When benzene vapors are inhaled, the benzene diffuses rapidly through the lungs and is quickly absorbed into the blood. Acute circulatory failure resulting in death within minutes often accompanies exposure to benzene concentrations as high as 20,000 ppm. Other acute effects of exposure to milder, though still high (250–500 ppm), concentrations of benzene include vertigo, nervous excitation, headache, nausea, and breathlessness. When exposure is stopped, rapid recovery from these symptoms usually occurs.

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air, it is produced in substantial quantities by the petroleum and steel industries. The production of benzene is rapidly expanding, and at present only eleven other chemicals and only one other hydrocarbon are produced in greater tonnage in the United States. *See* 43 Fed. Reg. 5918.

[9] According to the rubber companies, the manufacture of tires requires the use of petroleum solvents which generally contain small amounts of benzene.

The most common nonmalignant effects of chronic exposure to low[10] benzene concentration levels are a nonfunctioning bone marrow and deficiencies in the formed elements of the blood.[11] The degree of severity of such disorders ranges from mild and transient episodes to severe and fatal effects. Chromosomal aberrations have also been associated with chronic benzene exposure, and dermatitis or other dermal infections can be caused by direct bodily contact with liquid benzene.

As a result of its toxicity, benzene's history has been one of regulation. In 1946, the American Conference of Governmental Industrial Hygienists recommended a threshold limit value for benzene exposure of 100 ppm. This value was reduced to 50 ppm in 1947, to 35 ppm in 1948, to 25 ppm in 1963, and to 10 ppm in 1974. The American National Standards Institute adopted a threshold limit value of 10 ppm in 1969, which OSHA adopted in 1971 without rulemaking under the authority of 29 U.S.C.A. § 665(a).[12] This standard, codified at 29 C.F.R. § 1910.1000 Table Z–2 (1977)

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[10] These toxic effects were documented at exposure levels above 25-40 ppm, and a few studies showed nonmalignant blood abnormalities at levels below 25 ppm. 43 Fed. Reg. 5924-25.

[11] A decline in the red blood cell count (anemia) results in a decreased capacity of the blood to carry oxygen to various parts of the body and is characterized by fatigue. A decline in the white blood cell count (leukopenia) reduces the capacity of the body to defend against disease and is characterized by recurrent infections. A decline in the platelet count (thrombocytopenia) results in an impaired clotting of the blood and is characterized by bleeding tendencies.

[12] 29 U.S.C.A. § 655(a) directed the Secretary, within two years after the effective date of the Act and without rulemaking, to promulgate as an occupational safety or health standard any national consensus standard that he determined would result in improved safety or health for employees. The purpose of this power was to make the Act effective immediately, and the power expired on April 28, 1973.

and still in effect, was based on the nonmalignant toxic effects of benzene exposure and not on any possible leukemia hazard.

Widely scattered through the benzene literature are studies suggesting a link between benzene exposure and leukemia, a usually fatal cancer of the blood-forming organs. During the 1970's several additional studies reported a statistically significant increased risk of leukemia among workers occupationally exposed to high levels of benzene and concluded benzene was a leukemogen.[13] As a result of

[13] One such study was reported in 1975 by Dr. Enrico Vigliani. In 1963, Dr. Vigliani participated in a study of workers exposed to resins, inks, varnishes, and glues containing various amounts of benzene, and found a risk of leukemia among these workers twenty times greater than that for the general population. Toluene was substituted for benzene in 1964 in one of the industries studied, and the 1975 study showed no new cases of leukemia among workers in that industry.

A second study was reported in 1972 by Dr. Muzaffer Aksoy, a hematologist who testified at the rulemaking hearing. In this study Dr. Aksoy reported four leukemia deaths among Turkish shoemakers resulting from their exposure to benzene concentrations in excess of 150 ppm for periods ranging from six to fourteen years, and at the hearing he estimated that the incidence of leukemia among the population he studied was twice what would have been expected for the population as a whole. Dr. Aksoy also noted a decline in leukemia cases after other solvents were substituted for benzene.

The study most heavily relied upon by OSHA was one reported by Dr. Peter Infante of the National Institute for Occupational Safety and Health, a body created to conduct research and recommend occupational safety and health standards. *See* 29 U.S.C.A. §§ 669-71. Dr. Infante studied workers exposed to benzene in the production of Pliofilm at Goodyear's Akron and St. Mary's plants between 1940 and 1949 and found among them a five-fold increased risk of dying of leukemia when compared to two control groups. No specific exposure level during the period covered by the study was established, but testimony at the hearing indicated that exposure was probably around 100 ppm during most of the period studied with occasional exposure levels as high as several hundred parts per million.

this new evidence, OSHA began procedures which culminated with the present proposal, among other things, to reduce the permissible exposure level from 10 ppm to 1 ppm.

In January 1977 OSHA issued voluntary Guidelines for Control of Occupational Exposure to Benzene recommending exposure not to exceed an eight-hour time-weighted average of 1 ppm. An Emergency Temporary Standard for Occupational Exposure to Benzene also providing for a reduction in the permissible exposure limit to 1 ppm[14] was issued in May 1977, but this standard never went into effect because of judicial challenges. The proposed permanent benzene standard, which was based on OSHA's determination that the available scientific evidence established that employee exposure to benzene presents a leukemia hazard and that exposure therefore should be limited to the lowest feasible level, was published on May 27, 1977. This proposal provided for a reduction in the permissible exposure limit from 10 ppm to 1 ppm and established requirements relating to dermal and eye contact,[15] exposure monitoring, medical surveillance, methods of compliance, labeling, and recordkeeping. Public hearings were held July 19 through August 10, 1977, at which 95 witnesses testified. In addition, numerous exhibits and documents were submitted to OSHA as part of the rulemaking record. The resulting permanent benzene standard was promulgated on February 3 and published on February 10, 1978, with a March 3, 1978 effective date.

[14] Both the Guidelines and the Emergency Temporary Standard exempted work operations where the only exposure to benzene was from liquids containing 1 percent or less of benzene by volume.

[15] The proposed permanent statement also exempted work operations where the only exposure to benzene was from liquid mixtures containing 1 percent (0.1 percent after one year from the effective date of the standards) or less of benzene by volume.

III.

The American Petroleum Institute on behalf of itself and member companies filed petitions for review of the standard in this court on February 2 and February 3, 1978. The American Iron and Steel Institute, the Independent Petroleum Association of America, the Manufacturing Chemists Association, the Rubber Manufacturers Association, the Armstrong Rubber Company and Uniroyal, Inc., E. I. du Pont de Nemours and Company, and the Chemical Specialties Manufacturers Association subsequently either intervened on behalf of the American Petroleum Institute or filed original petitions for review in other circuits that were transferred to this circuit and consolidated with the American Petroleum Institute case. In addition, the Industrial Union Department, AFL-CIO, intervened on behalf of OSHA in support of the standard. [16]

The petitioners filed motions for a stay of the standard pending review on March 10, 1978, and on March 13 a judge of this court issued a temporary stay of the standard pending a hearing before a three-judge panel. The issues concerning the stay were fully briefed by the parties on an expedited basis, and after hearing oral argument a panel of the court on April 18, 1978, ordered a stay of the standard to be continued pending disposition of the petitions for review.[17]

The principal argument of the petitioning producers of benzene and benzene-containing products is that substantial evidence and the best available evidence do not show that the reduction of the permissible exposure limit from 10

[16] Although we speak generally in this opinion about the contentions of the petitioners and the contentions of OSHA, the Industrial Union Department was an active participant in this case and offered considerable support to OSHA's position.

[17] The issuance of a stay pending judicial review is authorized by 29 U.S.C.A. § 655(f).

ppm to 1 ppm is reasonably necessary or appropriate to provide safe or healthful employment and places of employment. These petitioners also attack several of the ancillary provisions of the standard, including its broad scope, the monitoring and medical surveillance requirements, and the specification of mandatory primary means of compliance, as not being supported by substantial evidence that they are reasonably necessary or appropriate to provide safe or healthful employment. The attack of the petitioning users of benzene and benzene-containing products is twofold: (i) They contend that substantial evidence and the best available evidence do not show that the dermal contact prohibition is reasonably necessary or appropriate to provide safe or healthful employment, and that the dermal contact prohibition is not feasible; and (ii) they contend that substantial evidence does not show the labeling requirement to be reasonably necessary or appropriate to provide safe or healthful employment, that the labeling requirement is not feasible, and that the labeling requirement is beyond OSHA's jurisdiction. OSHA, in addition to arguing that substantial evidence, the best available evidence, feasibility considerations, and its statutory mandate to protect workers justify the standard in its entirety, contends that Congress imposed on it no substantive requirement to promulgate only standards that are reasonably necessary or appropriate to provide safe or healthful employment and places of employment.

On June 21, 1978, the day before oral argument, OSHA promulgated an amended standard to exempt from the scope of the benzene standard work operations where the only exposure to benzene is from liquid mixtures containing 0.5 percent (0.1 percent after June 28, 1981) or less of benzene by volume, and to exempt from the labeling requirements liquid mixtures containing 5.0 percent or less benzene by volume which were packaged before June 27, 1978. 43 Fed.Reg. 27,971 (1978). Although the proposed emergency

temporary standard and the proposed permanent standard had exempted work operations where exposure to benzene resulted only from liquid mixtures containing 1 percent or less of benzene by volume,[18] the permanent standard that was promulgated contained no such exemption. As a result, the permanent standard prohibited all dermal contact with liquids containing any amount of benzene and it imposed the labeling requirements on all such liquids. Several industry groups petitioned OSHA for a stay of the dermal contact prohibition and labeling requirements as they applied to liquids containing small amounts of benzene.[19] OSHA subsequently granted a stay as to work operations where the sole exposure to benzene was from mixtures containing 0.1 percent or less of benzene and instituted a new rulemaking proceeding which resulted in the June 21, 1978 amendment.

The court called for supplemental briefing to address the effect of this amendment on the issues already briefed and argued. This briefing has been completed, and it appears that the major effect of the amendment is on the arguments regarding the feasibility of the dermal contact and labeling provisions. Since the considerations associated with the feasibility of those provisions have been significantly changed by the amendments, we do not address the merits of the feasibility arguments in this opinion.

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[18] As noted above, the exemption in the proposed permanent standard fell to 0.1 percent after the first year.

[19] These petitioners, who generally were among the user petitioners in this case, sought relief on the grounds that OSHA failed to provide adequate notice that the final standard might contain no exemption for work operations where the only benzene exposure was from liquid mixtures containing small amounts of benzene, that the dermal contact prohibition was not based on the best available evidence, and that the dermal contact prohibition was not feasible. With respect to feasibility, the rubber industry contended that the manufacture of tires was impossible without some dermal contact with solvent containing trace amounts of benzene.

IV.

OSHA justifies the reduction of the permissible exposure limit for benzene from 10 ppm to 1 ppm by coupling two factual findings, which it contends are supported by substantial evidence in the record, with a regulatory policy which OSHA contends is required by its mandate to protect workers. The factual findings are that benzene causes leukemia and that there presently exists no known safe level for benzene exposure. The regulatory policy is to limit employee exposure to carcinogens to the lowest feasible level.

The producer petitioners, in addition to attacking the factual finding that no known safe level for benzene exposure exists,[20] contend that OSHA has failed to meet a burden which the Act imposes of determining that the reduction of the permissible exposure limit from 10 ppm to 1 ppm is "reasonably necessary" to provide a safe workplace. In support of the latter contention, these petitioners point to this circuit's recent decision in *Aqua Slide 'N' Dive Corp* v. *Consumer Product Safety Commission*, 569 F.2d 831 (5th Cir. 1978), and assert that OSHA failed to assess benefits expected to be achieved by the standard in light of the expected costs of compliance. The petitioners argue that by defining an "occupational safety and health standard" as one requiring conditions "reasonably necessary" to provide safe or healthful places of employment, 29 U.S.C.A. §652(8), Congress recognized that safety and health resources are not unlimited and required OSHA somewhere in its decisionmaking process to (1) attempt to determine the extent to which its standards will benefit workers, and

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[20] This argument is based on the fact that all studies associating benzene and leukemia involve high benzene concentration levels, that a substantial body of the scientific community subscribes to the theory that safe threshold levels exist for exposure to carcinogens, and that empirical evidence shows that low-level exposure to benzene does not cause leukemia.

(2) decide whether the projected benefits justify the costs of compliance with the standard. Only if all standards are subjected to such assessment, argue the petitioners, can OSHA assure maximum benefit from the finite amount industry can expend on safety and health and thus carry out Congress' overriding policy "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions." 29 U.S.C.A. § 651(b). Since OSHA has not made a valid determination that reducing the permissible exposure level of benzene from 10 ppm to 1 ppm is reasonably necessary to protect workers from a risk of leukemia, the producers ask us to set that part of the standard aside.[21]

OSHA denies that the "reasonably necessary" language imposes any substantive obligation on it in promulgating standards. OSHA would distinguish *Aqua Slide*, which dealt with the Consumer Product Safety Act, on the basis that the "reasonably necessary" language in that Act appeared as a part of the sections which dealt with the agency's process of setting standards, 15 U.S.C.A. §§ 2056 (a), 2058(c)(2(A), whereas the "reasonably necessary" counterpart in the act it administers appears only in the section which defines the type of standard it may promulgate.

In authorizing the Consumer Product Safety Commission to promulgate safety standards, Congress provided that "[a]ny requirement of such a standard shall be reasonably necessary to prevent or reduce an unreasonable risk of injury associated with such product." 15 U.S.C.A. § 2056(a). It also required the Consumer Product Safety Commission to make a specific finding that its rules were "reasonably necessary to eliminate or reduce an unreasonable risk of injury." 15 U.S.C.A. § 2058(c)(2)(A). Rather

[21] As a corollary, they ask us to set aside all other provisions designed to effectuate the 1 ppm permissible exposure limit.

than following this format, the Occupational Safety and Health Act defines the occupational safety and health standard it authorizes as one "which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment." 29 U.S.C.A. § 652(8). We decline to construe the precisely similar requirements of these two Acts differently or to read words out of the OSHA legislation. The Act imposes on OSHA the obligation to enact only standards that are reasonably necessary or appropriate to provide safe or healthful workplaces. If a standard does not fit in this definition, it is not one that OSHA is authorized to enact.

OSHA next argues that even if the conditions required by occupational safety and health standards must be reasonably necessary to provide safe or healthful places of employment, the Act still imposes on OSHA no obligation to undertake a cost-benefit analysis with respect to the standards it promulgates. OSHA argues that 29 U.S.C.A. § 655(b)(5) defines when conditions imposed by a standard dealing with toxic materials are reasonably necessary. It urges that the emphasis of that section on making of a standard "which most adequately assures . . . that no employee will suffer material impairment of health . . . [from] regular exposure . . . for the period of his working life," overcomes any requirement to make a cost-benefit analysis. Nevertheless, OSHA contends that it did undertake economic analyses of both costs and benefits associated with the standard as required by *Aqua Slide*, and that after assessing those analyses it promulgated the standard.

Although 29 U.S.C.A. § 655(b)(5) requires the goal of attaining the highest degree of health and safety protection for the employee, it does not give OSHA the unbridled discretion to adopt standards designed to create absolutely risk-free workplaces regardless of cost. To the contrary,

that section requires standards to be feasible, and it contains a number of pragmatic limitations in the form of specific kinds of information OSHA must consider in enacting standards dealing with toxic materials. Those include "the best available evidence," "research, demonstrations, experiments, and such other information as may be appropriate," "the latest available scientific data in the field," and "experience gained under this and other health and safety laws." Moreover, in standards dealing with toxic materials, just as with all other occupational safety and health standards, the conditions and other requirements imposed by the standard must be "reasonably necessary or appropriate to provide safe or healthful employment and places of employment." 29 U.S.C.A. § 652(8).

Since the purpose of the Act to protect workers from dangerous conditions of employment is parallel to the purpose of the Consumer Product Safety Act to protect consumers from dangerous products, we must be guided by *Aqua Slide* in determining whether OSHA has met its burden of showing that the benzene standard is reasonably necessary to protect workers from a leukemia hazard. There we said:

> In evaluating the "reasonable necessity" for a standard, the Commission has a duty to take a hard look, not only at the nature and severity of the risk, but also at the potential the standard has for reducing the severity or frequency of the injury, and the effect the standard would have on the utility, cost or availability of the product.

569 F.2d at 844; *see also D. D. Bean & Sons* v. *Consumer Product Safety Commission,* 574 F.2d 643 (1st Cir. 1978). Before it regulates, the agency must show that a hazard exists and that its regulation will reduce the risk from the hazard, for "no [occupational safety and health] standard would be expected to impose added costs or inconvenience . . . unless there is reasonable assurance that the frequency

or severity of injuries or illnesses will be reduced." 569 F.2d at 839. More importantly for today's case, *Aqua Slide* also requires the agency to assess the expected benefits in light of the burdens to be imposed by the standard. Although the agency does not have to conduct an elaborate cost-benefit analysis, 569 F.2d at 840, it does have to determine whether the benefits expected from the standard bear a reasonable relationship to the costs imposed by the standard. 569 F.2d at 842.

The only way to tell whether the relationship between the benefits and costs of the benzene standard is reasonable is to estimate the extent of the expected benefits and costs. *See* 569 F.2d at 843. OSHA did this with respect to costs by engaging a consulting firm to assess the expected compliance costs and economic feasibility of the proposed standard. 43 Fed.Reg. 5934–39. Based on this study and other evidence, OSHA estimated compliance costs for all affected industries to be $187–205 million first year operating costs, $266 million engineering control costs, and $34 million recurring annual costs.[22] OSHA determined these costs to be feasible since they would not threaten the financial welfare of the affected firms or the general economy. However, OSHA disclaimed any obligation to balance these costs against expected benefits. 43 Fed.Reg. 5940–41. Rather than attempting to measure the extent to which the leukemia hazard of benzene exposure would be reduced by lowering the permissible exposure limit from 10 ppm to 1 ppm, OSHA merely assumed that benefits from the reduction "may be appreciable." It based this assumption on a finding that benzene was unsafe at any level and its conclusion

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[22] Although the petitioners do not seriously challenge OSHA's estimate of costs in this suit, they refer to the promulgation of this standard as a $1 billion decision.

Neither OSHA's estimate nor the petitioners' estimate takes into account the effects of the amendment, which narrows the scope of the standard.

that exposures to lower levels of toxic materials would be safer than exposure to higher levels.

OSHA's fall-back position attempts to justify its standard as being reasonably necessary within the meaning of *Aqua Slide*. It contends the standard promises appreciable benefits at a cost which industry can absorb. This justification is deficient in one crucial way: substantial evidence does not support OSHA's conclusion that benefits are likely to be appreciable. Without an estimate of benefits supported by substantial evidence, OSHA is unable to justify a finding that the benefits to be realized from the standard bear a reasonable relationship to its one-half billion dollar price tag.

OSHA's assumption that the standard is likely to result in benefits is not unsupported. The divided opinion in the scientific community over the existence or not of safe threshold levels of exposure to carcinogens provides substantial evidence which would support the finding that exposure to benzene at the present level of 10 ppm poses some leukemia risk. The general agreement in the scientific community that exposure to carcinogens at low levels is safer than exposure at higher levels permits the further factual deduction that reducing the permissible exposure limit from 10 ppm to 1 ppm will result in some benefit. This finding and deduction, however, does not yield the conclusion that measurable benefits will result, and OSHA is unable to point to any studies or projections supporting such a finding. As we noted in *Aqua Slide*, mere rationality is not equivalent to substantial evidence that conditions required by standards are reasonably necessary. 569 F.2d at 841. The lack of substantial evidence of discernible benefits is highlighted when one considers that OSHA is unable to point to any empirical evidence documenting a leukemia risk at 10 ppm even though that has been the permissible exposure limit since 1971. OSHA's assertion that benefits from reducing the permissible exposure limit from 10 ppm to 1 ppm are likely

to be appreciable, an assumption based only on inferences drawn from studies involving much higher exposure levels rather than on studies involving these levels or sound statistical projections from the high-level studies, does not satisfy the reasonably necessary requirement limiting OSHA's action. *Aqua Slide* requires OSHA to estimate the extent of expected benefits in order to determine whether those benefits bear a reasonable relationship to the standard's demonstrably high costs.

We are not persuaded by OSHA's argument that this standard should be upheld since the lack of knowledge concerning the effects of exposure to benzene at low levels makes an estimate of benefits expected from reducing the permissible exposure level impossible.[23] The statute requires all conditions imposed by a standard to be reasonably necessary to provide safe or healthful employment, and it requires decisions to be based on "the best available evidence," "research, demonstrations, experiments, and such other information as may be appropriate," "the latest

[23] Although OSHA asserts that risk quantification at low exposure levels and therefore estimates of expected benefits from the standard cannot presently be made, OSHA has provided us with a Preliminary Report on Population Risk to Ambient Benzene Exposures, recently released by the Environmental Protection Agency, which attempts to extrapolate from the results of the Infante study a determination of the risk of leukemia to the general population at the exposure level of 1 part per billion. In addition, the petitioners introduced at the rulemaking proceeding a preliminary risk assessment for occupational exposure to benzene at 10 ppm and 1 ppm based on the studies at higher exposure levels relied on by OSHA. Finally, OSHA's economic consultant testified that it could perform a cost-effectiveness analysis for the benzene standard; an analysis which would have included some kind of risk quantification. Although OSHA's assertion that present knowledge is insufficient to construct a valid dose-response curve for benzene may be correct, the record reflects that preliminary assessments are now being made and that valid extrapolations will be possible as more is known about the effects of past exposure at higher levels.

scientific data in the field," and "experience gained under this and other health and safety laws." By requiring the consideration of such kinds of information, Congress provided that OSHA regulate on the basis of knowledge rather than on the unknown. *But see Society of Plastics Industry, Inc.* v. *OSHA*, 509 F.2d 1301, 1308 (2d Cir. 1975). Until OSHA can provide substantial evidence that the benefits to be achieved by reducing the permissible exposure limit from 10 ppm to 1 ppm bear a reasonable relationship to the costs imposed by the reduction, it cannot show that the standard is reasonably necessary to provide safe or healthful workplaces.

This does not mean that OSHA must wait until deaths occur as a result of exposure at levels below 10 ppm before it may validly promulgate a standard reducing the permissible exposure limit. *See Florida Peach Growers Association, Inc.* v. *United States Department of Labor*, 489 F.2d 120 132 (5th Cir. 1974). Nevertheless, OSHA must have some factual basis for an estimate of expected benefits before it can determine that a one-half billion dollar standard is reasonably necessary. For example, when studies of the effects of human exposure to benzene at higher concentration levels in the past are sufficient to enable a dose-response curve[24] to be charted that can reasonably be projected to the lower exposure levels, or when studies of the effects of animal exposure to benzene[25] are sufficient to make projec-

[24] A dose-response curve shows the relationship between different exposure levels and the risk of cancer associated with those exposure levels. Generally, exposure to higher levels carries with it a higher risk, and exposure to lower levels is accompanied by a reduced risk.

[25] Although there have been attempts to demonstrate the development of leukemia in animals exposed to benzene, those attempts for the most part have been unsuccessful. Those studies do not even establish that benzene exposure causes leukemia, much less the degree of risk associated with various exposure levels. *See* 43 Fed. Reg. 5930-31, 5932.

tions of the risks involved with exposure at low levels, then OSHA will be able to make rough but educated estimates of the extent of benefits expected from reducing the permissible exposure level from 10 ppm to 1 ppm. Until such estimates are possible, OSHA does not have sufficient information to determine that a standard such as the one under review which it can only say might protect some worker from a leukemia risk is reasonably necessary.

We will not attempt to reconcile our decision with the cases from other circuits which uphold other standards, regulating exposure to carcinogens. *See Industrial Union Department, AFL-CIO* v. *Hodgson*, 162 U.S.App.D.C. 331, 499 F.2d 467 (1974) (asbestos dust standard); *Society of Plastics Industry, Inc.* v. *OSHA*, 509 F.2d 1301 (2d Cir. 1975) (vinyl chloride standard); *American Iron & Steel Institute et al.* v. *OSHA*, 577 F.2d 825, No. 76–2358 *et al.* (3d Cir., filed March 28, 1978) (coke oven emission standard). Those opinions did not address what Congress meant by requiring the conditions imposed by standards to be reasonably necessary to provide safe or healthful places of employment. In this circuit, under our *Aqua Slide* decision, substantial evidence must support a finding that those conditions are reasonably necessary, a showing that OSHA has not made. In addition, those cases were decided on their own records. Without critical analysis of what was established in those proceedings, we hold in today's case that Congress intended for OSHA to regulate on the basis of more knowledge and fewer assumptions than this record reflects.

OSHA's failure to provide an estimate of expected benefits for reducing the permissible exposure limit, supported by substantial evidence, makes it impossible to assess the reasonableness of the relationship between expected costs and benefits. This failure means that the required support is lacking to show reasonable necessity for the standard promulgated. Consequently, the reduction of the permissible

exposure limit from 10 ppm to 1 ppm and all other parts of the standard geared to the 1 ppm level must be set aside.

V.

OSHA's prohibition of dermal contact with benzene is based on "OSHA's policy that, in dealing with a carcinogen, all potential routes of exposure (*i.e.*, inhalation, ingestion, and skin absorption) be limited to the extent feasible." 43 Fed.Reg. 5948. OSHA, while acknowledging that the record evidence on the effect of benzene on the skin is "extremely limited" and that the few studies in the area "are not definitive as to the extent of benzene that is absorbed through the intact skin or as to the comparative rate of absorption through damaged skin," 43 Fed.Reg. 5948–49, nevertheless decided to prohibit dermal contact with liquids containing benzene. In arriving at this decision OSHA relied on animal studies and one human study suggesting that benzene is absorbed through intact skin, on the assumption that benzene would more readily be absorbed through damaged skin than undamaged skin, and on the belief that substances containing benzene are readily absorbed through the skin and act as vehicles for absorption of benzene.

OSHA now seeks in part to justify this prohibition as an adjunct to the permissible exposure limit for airborne concentrations of benzene and because of a concern for dermatitis. To the extent that the dermal contact prohibition is an adjunct of the permissible exposure limit, it would have to be set aside along with the permissible exposure limit. The concern for dermatitis, on the other hand, appears to be a post hoc rationalization for the dermal contact prohibition since it was not a significant part of OSHA's reasoning process that led to this provision.[26] The requirements of

[26] At one point in the statement of reasons for the benzene standard OSHA did state that "[o]ne purpose of the protective clothing and equipment requirement is to protect employees from dermatitis and burns." 43 Fed. Reg. 5953. The reason for this standard as a whole, however, and the primary reason for the absolute prohibition of dermal contact with benzene (to which the protective clothing and equipment provision is tied), is to protect workers from a suspected carcinogen. It is within the context of OSHA's policy of reducing exposure to carcinogens to the lowest feasible level that we must review the dermal contact prohibition.

Dermal diseases can pose significant hazards in the workplace, and regulatory action following proceedings specifically focusing on such hazards may be appropriate. OSHA recently announced the formation of a standards advisory committee on cutaneous hazards to "identify the occupational exposures in industry which pose a hazard to the skin and/or the use of the skin as a portal of entry." 43 Fed. Reg. 10,647-48 (1978).

this standard were based on the possible leukemia hazard associated with exposure to benzene, 43 Fed.Reg. 5918, 5948, and our review must be of the reasoning process of the agency at the time it promulgated the standard based on the record before it. *Dry Color Manufacturers' Association, Inc. v. Department of Labor*, 486 F.2d 98, 104 n.8 (3d Cir. 1973).

The user petitioners contend that substantial evidence and the best available evidence do not support a finding that the dermal contact provisions are reasonably necessary to provide safe or healthful employment, and in addition they contend that the dermal contact prohibition is not feasible since it is impossible for certain industries to operate without some dermal contact with liquids containing small amounts of benzene. Since the amendment to the standard on June 21, 1978, significantly affects the feasibility issue, we will not address that issue in this opinion. We agree with the users, however, that OSHA has not shown the dermal contact prohibition to be reasonably necessary to protect workers from contracting benzene-related leukemia since readily available evidence of the kind Congress required OSHA to consider was neglected. The record therefore fails to support the finding that benzene is absorbed through the skin. Since entry to the body by dermal contact was not established, the record will not support a finding

that the prohibition of all dermal contact with benzene will result in quantifiable benefits in terms of a reduced risk of leukemia justifying the costs of the provision. Thus reasonable necessity is lacking here too.

Studies of whether benzene is absorbed by the skin of animals, conducted in the first half of this century, are referred to in this record during the course of expert testimony and as background material in later studies of whether benzene can be absorbed by human skin. Though these studies reached different conclusions, their relevance with respect to the issue of absorption of benzene by human skin has been questioned since there are important differences between the permeability of the skins of animals and humans. The studies concluding that benzene penetrates skin of certain animals have also been criticized since the possibility of benzene inhalation was not excluded and since there was no guarantee that the skin remained intact through the course of the experiment.

Between 1946 and 1961, experiments were conducted to determine whether human skin absorbed benzene. Although the first several of these studies conducted in the late 1940's and mid-1950's had negative results, one study published in 1961 found that some absorption had occurred and concluded that "the absorption of benzene throughout the skin must not be neglected." The record reveals problems in the interpretation of all of these studies, however. In particular, the 1961 study reporting positive results used a technique, compressing benzene-soaked cotton against the skin with a glass plate for prolonged periods, that is recognized today as an efficient way to drive molecules into the skin.

The oral testimony on the issue of skin absorption of benzene is very limited. Representatives of the National Institute of Occupational Safety and Health testified that they were of the opinion that benzene can be absorbed through the skin, and that absorption is more likely when the skin is damaged or when the benzene is contained in a

solvent which itself is absorbed. Except for a passing reference to what appears to be the 1961 positive study, these witnesses did not attempt to support their opinions by reference to empirical data.

The one expert dermatologist who testified in depth on the issue of skin absorption of benzene, Dr. Howard Maibach of the University of California Medical Center, after summarizing and discussing critically the studies that have been conducted to date, concluded that "in 1977 it is extremely difficult, if not impossible, to balance all of the information that is available. Admittedly, the overwhelming majority of the observations suggest that benzene does not penetrate the skin. One observation suggests that it does." Dr. Maibach testified that he did not know whether benzene is absorbed through the skin; that he did not know whether benzene would be more readily absorbed through damaged skin than intact skin, although the assumption, unsupported by any data, is that it would be; and that he did not know whether benzene would be absorbed more readily if it is in another solvent.

Were this the extent of the record on the issue of skin absorption, OSHA's finding that dermal contact with benzene poses a cancer risk could pass muster. When available evidence of equivalent quality is conflicting, a finding in accordance with one view or the other should be considered to be supported by substantial evidence. *See Universal Camera Corp.* v. *NLRB*, 340 U.S. 474, 488, 71 S.Ct. 456, 465, 95 L.Ed. 456 (1951). This record speaks further on the issue of skin absorption, however, and in light of OSHA's statutory command this additional evidence removes the support for OSHA's actions.

Dr. Maibach, following his conclusion that the studies conducted to date were not definitive on the issue of whether human skin absorbed benzene, stated:

> Today we have a much simpler and much more direct way of answering this . . . because now radioactive

> benzene is available, and one simply would apply radioactive benzene, some Carbon 14 benzene, to the skin of the arm of an appropriate animal that has permeability characteristics similar to the people in this room . . . and then would simply look for the radioactivity excreted into the urine, the feces and the breath.
>
> This is a simple technique. It has been done for over 100 organic compounds in the last decade, measuring the amount of transport to the skin, and it would then tell us definitively, without argument, and efficiently, just how much of any benzene penetrates the skin.

Dr. Maibach testified that this experimental technique can answer a number of questions other than whether any benzene penetrates the skin, including demonstrating any differences in existence and extent of absorption of various parts of the body which may be exposed; whether benzene applied to the skin has the same toxic potential as benzene inhaled; whether multiple exposures result in correspondingly greater absorption than a single exposure; whether it is possible for one to protect himself by wearing protective clothing; whether and to what extent the amount of benzene absorbed through the skin is dependent upon benzene concentration; whether, because of its volatility, benzene splashed onto the skin evaporates more rapidly or goes through the skin more rapidly; and whether benzene is absorbed more readily if it is in another solvent. Dr. Maibach testified that the experiment would be relatively short term in length (six to twelve weeks), that the techniques are straightforward and reliable, and that the experiment could be done by anybody having the analytic facilities available. This testimony about the availability and reliability of modern experimental techniques is unrefuted in the record.

OSHA's decision to regulate on the basis of dated, inconclusive data when modern experimental methods can quickly and efficiently provide reliable information contravenes the directive from Congress to promulgate standards on the basis of the "best available evidence," "research, demonstrations, experiments, and such other information as may be appropriate," and "the latest available scientific data in the field." 29 U.S.C.A. § 655(b)(5). This is not a case where there is testimony that additional sophisticated research could be attempted, but might not shed new light on a subject. To the contrary, unrefuted testimony reveals the existence of simple experimental techniques, tried and proved effective for over 100 organic compounds, that can provide accurate information on the factual issues OSHA admits are unresolved by the past studies.[27] When such factual information is so readily available, 29 U.S.C.A. § 655(b)(5) requires OSHA to acquire that information before promulgating regulations which would require an established industry to change long-followed work processes that are not demonstrably unsafe.

In light of unrefuted testimony on the ready availability of conclusive evidence on the subject, OSHA's choice to rely on old and inconclusive evidence that there is a possibility of absorption of benzene through the skin which might cause cancer is in clear disregard of the congressional directive as to the kinds of evidence OSHA is required to consider. Therefore, the provision of the standard prohibiting dermal contact with liquid benzene cannot stand on the present record.

VI.

The reduction of the permissible exposure limit and the prohibition of dermal contact are the provisions of the benzene standard to which all the standard's other requirements are tied. Since neither of these provisions can be upheld on the present record, it follows that the standard as a whole must be set aside.

Although we vacate the labeling provision in conjunction with the rest of the standard, this or some similar require-

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[27] In their brief the petitioners represent that Dr. Maibach is now conducting one such study.

ment is sure to be considered by OSHA on remand. Therefore, we address the user petitioners' jurisdictional attack on one aspect of that provision. The labeling provision generally requires the employer to assure that caution labels are affixed to all containers of benzene and benzene-containing products. In the aspect of the provision under attack, OSHA further requires each employer to "assure that the caution labels remain affixed when the benzene or products containing benzene are sold, distributed or otherwise leave the employer's workplace."

By requiring caution labels to remain affixed when benzene products leave an employer's workplace, OSHA intended to assure that all employees along the product's distribution chain are apprised of the hazardous nature of benzene exposure. 43 Fed.Reg. 5960. It relied on the authority given to it by 29 U.S.C.A. § 655(b)(7) to require the use of warning labels in standards, and it concluded that this authority was not limited to requiring an employer to warn his own employees of the hazardous products he manufactures. Since the manufacturer of a product containing a toxic substance (and subsequent employers who have been informed of the hazard) is in the best position to know of the hazard and warn others down the distribution chain, OSHA concluded that the protective purposes of the Act would best be served by requiring the manufacturers to refrain from taking steps designed to withhold information concerning the dangers of the products from downstream workers.

The petitioners contend that the Act gives OSHA the jurisdiction to regulate workplaces, not products. They argue that OSHA here is claiming the authority to regulate finished products leaving the workplace, an authority that would transform what was intended to be a federal workplace safety code into a federal product safety code. The petitioners contend that Congress intended to place the responsibility for protecting each employee on his or her

own employer, an allocation of responsibility that has proved workable in all but unusual circumstances such as the multiemployer construction worksite; and that, since all employers would be required to assure that benzene-containing products in their own workplaces are labeled, and the usual allocation of responsibility for labeling would be workable and effective.

Cases involving multiemployer construction worksites have recognized a duty on an employer to comply with OSHA standards in order to protect the employees of another employer. See *Brennan* v. *Occupational Safety & Health Review Commission and Underhill Construction Corp.*, 513 F.2d 1032 (2d Cir. 1975) *(Underhill)*; *Marshall* v. *Knutson Construction Co.*, 566 F.2d 596 (8th Cir. 1977); *Beatty Equipment Leasing, Inc.* v. *Secretary of Labor*, 577 F.2d 534 (9th Cir. 1978). These cases involved citations for violations of 29 U.S.C.A. § 654(a), which imposes two duties on employers:

> Each employer—
>
> (1) shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees;
>
> (2) shall comply with occupational safety and health standards promulgated under this chapter.

In holding that the § 654(a)(2) duty could be violated even though the cited employer's employees were not shown to have been exposed to the hazard created by the violation, the *Underhill* court emphasized that the § 654(a)(2) duty, unlike the § 654(a)(1) duty, was "in no way limited to situations where a violation of a standard is linked to exposure of *his* employees to the hazard." 513 F.2d at 1038 (emphasis in original). In reaching its conclusion, the court relied on the broad remedial purpose of the Act and on the fact that the cited employer had created the hazard and maintained

the area where it was located. In agreeing with this analysis, the *Beatty* court stated:

> [This interpretation of the statute] facilitates the broad remedial purpose of the Act which Congress declared is "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions." 29 U.S.C.A. § 651. As this court has stated, "Congress clearly intended to require employers to eliminate all foreseeable and preventable hazards." [citation omitted] We agree with the Commission that this policy can best be effectuated by placing the responsibility for hazards on those who create them.

577 F.2d at 537. The duty on one employer to comply with OSHA standards for the benefit of employees of another employer, however, has only been expressly recognized in the multiemployer construction worksite context.

In deciding whether an OSHA standard can require an employer to assure that a warning label remains affixed when a benzene-containing product leaves his workplace in order to protect downstream employees, we too must keep in mind the Act's overall purpose "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions." 29 U.S.C.A. § 651(b). In this light the provision of the statute requiring OSHA to prescribe labeling of hazards is broad in scope:

> Any standard promulgated under this subsection shall prescribe the use of labels or other appropriate forms of warning as are necessary to insure that employees are apprised of all hazards to which they are exposed . . .

29 U.S.C.A. § 655(b)(7). Unlike some sections of the Act, this provision does not expressly limit the employer's obligation of informing employees of hazardous conditions to the employer's own employees.

The ability of downstream employers to protect their own employees is also an appropriate consideration in determining where the duty to warn should lie. *Cf. Anning-Johnson Co.* v. *Occupational Safety and Health Review Commission*, 516 F.2d 1081, 1086–91 (7th Cir. 1975). This record reveals that the presence of benzene in a workplace is often a hidden hazard. Some industries refer to benzene under code or trade names, and many products containing benzene are sold only under trade names with no listing of contents. Under such circumstances it is apparent that the manufacturer of a benzene-containing product is in a far better position to warn downstream employees in operations using the benzene-containing product of the benzene hazard than is a downstream employer.

Considering the purpose of the Act to protect every working person in the nation, the express and broad statutory authorization for OSHA to prescribe warning labels in standards, and the fact that the presence of benzene in a product is often a concealed hazard, we agree with OSHA that it has the authority to prohibit an employer from removing the warning labels from containers of benzene and benzene products when those containers leave his workplace. This is not a situation where OSHA is imposing a heavy regulatory burden on an employer solely for the benefit of the employees of another. Rather, the regulation says no more than that an upstream employer may not take affirmative steps to withdraw from downstream employees a protection that he must furnish to his own employees. The obvious reluctance of the maker of a product to intimate or suggest to his consumers that his product is less than totally desirable is understandable. Such a consideration may even be shown to have such deleterious effect on sales that it affects the reasonable necessity for this feature of the regulation. *See Aqua Slide*, 569 F.2d at 840–43. In such a case, OSHA may choose to eliminate the requirement altogether. It may also choose to moderate the label's description to more precisely describe the nature or extent of the hazard.

Placing the responsibility to warn downstream employees of concealed hazards on those upstream employers who create the hazards and know of the hazards is consistent with the remedial purpose of the Act and is within OSHA's broad authority to prescribe warning labels. If on remand OSHA decides to promulgate a new benzene standard which includes warning labels, OSHA may require an employer in the chain of distribution of those products to assure that such warning labels remain affixed when the product leaves the employer's workplace provided, of course, the labeling requirement as a whole is shown to be reasonably necessary to provide safe workplaces.

The user petitioners also contend that OSHA's authority to require labeling of products containing benzene has been preempted under 29 U.S.C.A. § 653(b)(1)[28] by the Consumer Product Safety Commission, which has promulgated regulations under the Federal Hazardous Substances Act, 15 U.S.C.A. § 1261 *et seq.*,[29] requiring the labeling of products containing benzene. *See* 16 C.F.R. § 1500.14(a)(3), (b)(3) (1977). We reject this argument. The preemption provision was intended to avoid the "duplication that would result where another federal agency was also providing for the occupational safety of a class of workers." *Organized Migrants in Community Action, Inc.* v. *Brennan*, 172 U.S. App.D.C. 147, 153, 520 F.2d 1161, 1167 (1975). It applies only when the preempting regulation is "directed at a working condition," *Southern Pacific Transportation Co.* v. *Usery*, 539 F.2d 386, 391 (5th Cir. 1976), which the promulgating agency has authority to regulate. The Consumer Product Safety Commission's regulation is not designed to protect a class of workers and it is not directed at the working conditions of employees. Although an existing requirement for labeling under another act may affect the reasonable necessity for an OSHA requirement, 29 U.S.C.A. § 653(b)(1) does not prohibit OSHA from requiring containers of benzene products to bear the warning labels authorized by 29 U.S.C.A. § 655(b)(7).

[28] 29 U.S.C.A. § 653)b)(1) states:

> Nothing in this chapter shall apply to working conditions of employees with respect to which other Federal agencies . . . exercise statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health.

[29] The Consumer Product Safety Commission has authority to promulgate regulations under the Federal Hazardous Substances Act by virtue of 15 U.S.C.A. § 2079.

Conclusion

The petitions for review are granted. The reduction of the airborne permissible exposure limit from 10 ppm to 1 ppm is set aside since the present record does not show that such a reduction is reasonably necessary to provide safe or healthful employment. The dermal contact prohibition is set aside since this provision was not based on the best available scientific data in the field. The remaining provisions of the standard are also vacated since they are ancillary to the permissible exposure limit reduction and the dermal contact prohibition.

APPENDIX B

Part 1910 of Title 29 of the Code of Federal Regulations is hereby amended as follows:

1. A new paragraph (c) is added to § 1910.19, to read as follows:

§ 1910.19 *Special provisions for air contaminants.*

(c) Section 1910.1028 shall apply to the exposure of every employee to benezene in every employment and place of employment covered by §§ 1910.12, 1910.13, 1910.14, 1910.15, or § 1910.16, in lieu of any different standard on exposure to benzene which would otherwise be applicable by virtue of any of those sections.

§ 1910.20 [Revoked]

2. Section 1910.20 is revoked.

§ 1910.1000 [Amended]

3. Table Z-2 of § 1910.1000 is amended by adding a footnote following the words "Benzene (Z37.40-1969)," and by adding the following below Table Z-2:

4. Section 1910.1028 is revised to read as follows:

§ 1910.1028 Benzene.

(a) *Scope and application.* (1) This section applies to each place of employment where benzene is produced, reacted, released, packaged, repackaged, stored, transported, handled, or used.

(2) This section does not apply to:

(i) The storage, transportation, distribution, dispensing, sale or use as fuel of gasoline, motor fuels, or other fuels subsequent to discharge from bulk terminals; or

[1] Occupational exposures to benzene are subject to the requirements of § 1910.1028 except as specifically exempted by § 1910.1028(a)(2). Exposures exempted by § 1910.1028(a)(2) are covered by this § 1910.1000.

(ii) The storage, transportation, distribution or sale of benzene in intact containers sealed in such a manner as to contain benzene vapors or liquid, except for the requirements of paragraph (k) (2), (3), (4), and (5), and paragraph (j) of this section.

(b) *Definitions.* "Action level" means an airborne concentration of benzene of 0.5 ppm, averaged over an 8-hour work day.

"Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

"Authorized person" means any person required by his duties to enter a regulated area and authorized to do so by his employer, by this section or by the Occupational Safety and Health Act of 1970. "Authorized person" includes a representative of employees who is designated to observe monitoring and measuring procedures under paragraph (m) of this section.

"Benzene" (C_6H_6) (CAS Registry No. 00071432) means solid, liquefied or gaseous benzene. It includes mixtures of liquids containing benzene and the vapors released by these liquids.

"Bulk terminal" means a facility which is used for the storage and distrbution of gasoline, motor fuels or other fuels and which receives its petroleum products by pipeline, barge or marine tanker.

"Director" means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health, Education, and Welfare, or designee.

"Emergency" means any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment which may, or does, result in a massive release of benzene.

"OSHA Area Office" means the office of the Occupational Safety and Health Administration having jurisdiction over the geographic area where the affected workplace is located.

(c) *Permissible exposure limits*—(1)*Inhalation*—(i) *Time-weighted average limit (TWA).* The employer shall assure that no employee is exposed to an airborne concentration of benzene in excess of 1 part benzene per million parts of air (1 ppm) as an 8-hour time-weighted average.

(ii) *Ceiling limit.* The employer shall assure that no employee is exposed to an airborne concentration of benzene in excess of 5 ppm as averaged over any 15 minute period.

(2) *Dermal and eye exposure limit.* The employer shall assure that no employee is exposed to eye contact with liquid benzene; or to skin contact with liquid benzene, unless the employer can establish that the skin contact is an isolated instance.

(d) *Regulated areas.* (1) the employer shall establish, within each place of employment, regulated areas where benzene concentrations are in excess of the permissible airborne exposure limit.

(2) The employer shall limit access to regulated areas to authorized persons.

(3) *Notification of regulated areas.* Within 30 days following the establishment of a regulated area, the employer shall report the following information to the OSHA Area Office:

(i) The address of each establishment which has one or more regulated areas;

(ii) The locations, within the establishment, of each regulated area;

(iii) A brief description of each process or operation which results in employee exposure to benzene in regulated areas; and

(iv) The number of employees engaged in each process or operation within each regulated area which results in exposure to benzene, and an estimate of the frequency and degree of exposure within each regulated area.

(e) *Exposure monitoring and measurements.*—(1) *General.* (i) Determinations of airborne exposure levels shall be made from air samples that are representative of each employee's exposure to benzene over an eight (8) hour period.

(ii) For the purposes of this section, employee exposure is that exposure which could occur if the employee were not using a respirator.

(2) *Initial monitoring.* (i) Each employer, who has a place of employment where benzene is produced, reacted, released, packaged, repackaged, stored, transported, handled or used shall monitor each of these workplaces and work operations to accurately determine the airborne concentrations of benzene to which employees may be exposed.

(ii) The initial monitoring required under paragraph (e)(2)(i) of this section shall be conducted and the results obtained within 30 days of the effective date of this section. Where the employer has monitored after January 4, 1977 and the monitoring satisfies the accuracy requirements of paragraph (e)(6) of the section, the employer may rely on such earlier monitoring to satisfy the requirements of paragraph (e)(2)(i) of this section, unless there has been a production, process, personnel or control change which may have resulted in new or additional exposures to benzene or the employer has any other reason to suspect a change which may have resulted in new or additional exposures to benzene; and provided that the employer maintains a record of the monitoring in accordance with paragraph (l) (1) and notifies each employee in accordance with paragraph (e)(5).

(3) *Frequency.*—(i) *Measurements below the action level.* If the measurements conducted under paragraph (e)(2)(i)

of this section reveal employee exposure to be below the action level, the measurements need not be repeated, except as otherwise provided in paragraph (e)(4) of this section.

(ii) *Measurements above the action level.* If the measurements reveal employee exposure to be in excess of the action level, but below the permissible exposure limit, the employer shall repeat the monitoring at least quarterly. The employer shall continue these quarterly measurements until at least two consecutive measurements, taken at least seven (7) days apart, are below the action level, and thereafter the employer may discontinue monitoring, except as provided in paragraph (e)(4) of this section.

(iii) *Measurements above the permissible exposure limit.* If the measurements reveal employee exposure to be in excess of the permissible exposure limits, the employer shall repeat the measurements at least monthly. The employer shall continue these monthly measurements until at least two consecutive measurements, taken at least seven (7) days apart, are below the permissible exposure limits, and thereafter the employer shall monitor at least quarterly.

(4) *Additional monitoring.* Whenever there has been a production, process, personnel or control change which may result in new or additional exposure to benzene or whenever the employer has any other reason to suspect a change which may result in new or additional exposures to benzene, such as spills, leaks, ruptures, or breakdowns, the employer shall repeat the monitoring which is required by paragraph (e)(2)(i) of this section.

(5) *Employee notification.* (i) Within 5 working days after the receipt of the measurement results, the employer shall notify each employee in writing of the exposure measurements which represent that employee's exposures.

(ii) Where the results indicate that the employee's exposure exceeds the permissible exposure limits, the notification shall also include the corrective action being taken or to be taken by the employer to reduce exposure to or below the permissible exposure limit.

(6) *Accuracy of measurement.* The employer shall use a method of measurement which has an accuracy, to a confidence level of 95 percent, of not less than plus or minus 25 percent for concentrations of benzene greater than or equal to 1 ppm.

(f) *Methods of compliance.*—(1) *Priority of compliance methods.* The employer shall institute engineering and work practice controls to reduce and maintain employee exposures to benzene at or below the permissible exposure limits, except to the extent that the employer establishes that these controls are not feasible. Where feasible engineering and work practice controls are not sufficient to reduce employee exposure to or below the permissible exposure limits, the employer shall nonetheless use them to reduce exposures to the lowest level achievable by these controls, and shall supplement them by the use of respiratory protection.

(2) *Compliance program.* (i) The employer shall establish and implement a written program to reduce exposures to or below the permissible exposure limits solely by means of engineering and work practice controls required by paragraph (f)(1) of this section.

(ii) The written program shall include a schedule for development and implementation of the engineering and work practice controls. These plans shall be revised at least every six months to reflect the current status of the program.

(iii) Written plans for these compliance programs shall be submitted, upon request, to the Assistant Secretary and the Director, and shall be available at the worksite for examination and copying by the Assistant Secretary, the Director, and the employees or their authorized representatives.

(iv) The employer shall institute and maintain at least the controls described in his most recent written compliance program.

(g) *Respiratory protection.*—(1) *General.* Where respiratory protection is required under this section, the employer shall select, provide and assure the use of respirators. Respirators shall be used in the following circumstances:

(i) During the time period necessary to install or implement feasible engineering and work practice controls;

(ii) During maintenance and repair activities in which enginering and work practice controls are not feasible;

(iii) In work situations where feasible engineering and work practice controls are not yet sufficient to reduce exposure to or below the permissible exposure limits; or

(iv) In emergencies.

(2) *Respirator selection.* (i) Where respiratory protection is required under this section, the employer shall select and provide, at no cost to the employee, the appropriate respirator from Table 1 below and shall assure that the employee uses the respirator provided.

(ii) The employer shall select respirators from among those approved by the National Institute for Occupational Safety and Health under the program of 30 CFR Part 11.

(3) *Respirator program.* The employer shall institute a respiratory protection program in a accordance with § 1910.134(b), (d), (e) and (f).

(4) *Respirator use.* (i) Where air purifying respirators (cartridge, canister, or gas mask) are used, the employer shall, except as provided in paragraph (g)(4)(ii) of this section, replace the air-purifying canisters or cartridges prior to the expiration of their service life or the end of shift in which they are first used, whichever occurs first.

(ii) Where a cartridge or canister of an air purifying respirator has an end of service life indicator certified by NIOSH for benzene, the employer may permit its use until such time as the indicator shows the end of service life.

(iii) The employer shall assure that the respirator issued to the employee exhibits minimum facepiece leakage and that the respirator is properly fitted.

(iv) The employer shall allow each employee who wears a respirator to wash his or her face and respirator facepiece to prevent skin irritation association with respirator use.

TABLE I.—*Respiratory protection for benzene*

Airborne concentration of benzene or condition of use	*Respirator type*
(*a*) Less than or equal to 10 p/m.	(*1*) Any chemical cartridge respirator with organic vapor cartridge; or
	(*2*) Any supplied air respirator.
(*b*) Less than or equal to 50 p/m.	(*1*) Any chemical cartridge respirator with organic vapor cartridge and full facepiece;
	(*2*) Any supplied air respirator with full facepiece;
	(*3*) Any organic vapor gas mask; or
	(*4*) Any self-contained breathing apparatus with full facepiece.
(*c*) Less than or equal to 1,000 p/m.	(*1*) Supplied air respirator with half mask in positive pressure mode.

(*d*) Less than or equal to 2,000 p/m.	(*1*) Supplied air respirator with full facepiece, helmet, or hood, in positive pressure mode.
(*e*) Less than or equal to 10,000 p/m.	(*1*) Supplied air respirator and auxiliary self-contained facepiece in positive pressure mode; or (*2*) Open circuit self-contained breathing apparatus with full facepiece in positive pressure mode.
(*f*) Escape	(*1*) Any organic vapor gas mask; or (*2*) Any self-contained breathing apparatus with full facepiece.

(h) *Protective clothing and equipment.* Where eye or dermal exposure may occur, the employer shall provide, at no cost to the employee, and assure that the employee wears impermeable protective clothing and equipment to protect the area of the body which may come in contact with liquid benzene. Eye and face protection shall meet the requirements of § 1910.133 of this Part.

(i) *Medical Surveillance*—(1) *General.* (i) The employer shall make available a medical surveillance program for employes who are or may be exposed to benzene at or above the action level and employees who are subjected to an emergency.

(ii) The employer shall assure that all medical examinations and procedures are performed by or under the supervision of a licensed physician, and provided without cost to the employee.

(2) *Initial examinations.* (i) Within thirty days of the effective date of this section, or before the time of initial assignment, the employer shall provide each employee who

is or may be exposed to benzene at or above the action level with a medical examination, including at least the following elements;

(*a*) A history which includes past work exposure to benzene or any other hematologic toxins; a family history of blood dyscrasias including hematological neoplasms; a history of blood dyscrasias including genetically related hemoglobin alterations, bleeding abnormalities, abnormal function of formed blood elements; a history of renal or liver dysfunction; a history of drugs routinely taken, alcoholic intake and systemic infections; a history of exposure to marrow toxins outside of the current work situation, including volatile cleaning agents and insecticides;

(*b*) Laboratory tests, including a complete blood count with red cell count, white cell count with differential, platelet count, hematocrit, hemoglobin and red cell indices (MCV, MCH, MCHC), serum bilirubin and reticulocyte count; and

(*c*) Additional tests where, in the opinion of the examining physician, alterations in the components of the blood are related to benzene exposure.

(ii) No medical examination is required to satisfy the requirements of paragraph (i)(2)(i) of this section if adequate records show that the employee has been examined in accordance with the procedures of paragraph (i)(2)(i) of this section within the previous six months.

(3) *Information provided to the physician.* The employer shall provide the following information to the examining physician for each examination under this section:

(i) A copy of this regulation and its appendixes;

(ii) A description of the affected employee's duties as they relate to the employee's exposure;

(iii) The employee's representative exposure level or anticipated exposure level;

(iv) A description of any personal protective equipment used or to be used; and

(v) Information from previous medical examinations of the affected employee which is not readily available to the examining physician.

(4) *Physician's written opinions.* (i) For each examination under this section, the employer shall obtain and provide the employee with a copy of the examining physician's written opinion containing the following:

(*a*) The results of the medical examination and tests;

(*b*) The physician's opinion concerning whether the employee has any detected medical conditions which would place the employee's health at increased risk of material impairment from exposure to benzene;

(*c*) The physician's recommended limitations upon the employee's exposure to benzene or upon the employee's use of protective clothing or equipment and respirators.

(ii) The written opinion obtained by the employer shall not reveal specific findings or diagnoses unrelated to occupational exposures.

(5) *Periodic examinations* (i) The employer shall provide each employee covered under paragraph (i)(1)(i) of this section with a medical examination at least semi-annually following the initial examination. These periodic examinations shall include at least the following elements:

(*a*) A brief history regarding any new exposure to potential marrow toxins, changes in drug and alcohol intake and the appearance of physical symptoms relating to blood disorders;

(*b*) A complete blood count with red cell count, white cell count with differential, platelet count, hemoglobin, hematocrit and red cell indices (MCV, MCH, MCHC); and

(*c*) Additional tests where in the opinion of the examining physician, alterations in the components of the blood are related to benzene exposure.

(ii) Where the employee develops signs and symptoms commonly associated with toxic exposure to benzene, the employer shall provide the employee with a medical examination which shall include those elements considered appropriate by the examining physician.

(6) *Emergency situations.* If the employee is exposed to benzene in an emergency situation, the employer shall provide the employee with a urinary phenol test at the end of the employee's shift. The urine specific gravity shall be corrected to 1.024. If the result of the urinary phenol test is below 75 mg/ml, no further testing is required. If the result of the urinary phenol test is equal to or greater than 75 mg/ml, the employer shall provide the employee with a complete blood count including a red cell count, white cell count with differential, and platelet count as soon as practicable, and shall provide these same counts one month later.

(7) *Special examinations.* (i) Where the results of any tests required by this section reveal that any of the following conditions exist, the employer shall have the test results of the employee evaluated by a hematologist:

(*a*) The red cell count, hemoglobin or platelet count varies more than 15 percent above or below the employee's most recent values;

(*b*) The red cell count is below 4.4 million or above 6.3 million per mm^3, (for males), or below 4.2 million or above 5.5 million per mm^3 (for females);

(*c*) The hemoglobin is below 14 grams percent or above 18 grams percent (for males) or below 12 grams percent or above 16 grams percent (for females);

(*d*) The white cell count is below 4,200 or above 10,000;

(*e*) The thrombocyte count is below $140x10^9$ cells per mm^3 or above $440x10^9$ cells per mm^3.

(ii) In addition to the information required to be provided to the physician under paragraph (i)(3) of this section, the employer shall provide the hematologist with the medical record required to be maintained by paragraph (1)(2) of this section.

(iii) The hematologist's evaluation shall include a determination as to the need for additional tests, and the employer shall assure that these tests are provided.

(j) *Employee information and training*—(1) *Training program.* (i) The employer shall institute a training program for all employees assigned to workplaces where benzene is produced, reacted, released, packaged, repackaged, stored, transported, handled or used and shall assure that each employee assigned to these workplaces is informed of the following:

(*a*) The information contained in Appendices A and B of this section;

(*b*) The quantity, location, manner of use, release, or storage of benzene and the specific nature of operations which could result in exposure above the permissible exposure limits as well as necessary protective steps;

(*c*) The purpose, proper use, and limitations of personal protective equipment and clothing required by paragraph (h) of this section and of respiratory devices required by paragraph (g) of this section and § 1910.134(b), (d), (e) and (f);

(*d*) The purpose and a description of the medical surveillance program required by paragraph (i) of this section and the information contained in Appendix C of this section; and

(*e*) The contents of this standard.

(ii) The training program required under paragraph (j)(1)(i) of this section shall be provided within 90 days of the effective date of this section or at the time of initial assignment to workplaces where benzene is produced, reacted, released, packaged, repackaged, stored, transported, handled or used, and at least annually thereafter.

(2) *Access to training materials.* (i) The employer shall make a copy of this standard and its Appendices readily available to all affected employees.

(ii) The employer shall provide, upon request, all materials relating to the employee information and training program to the Assistant Secretary and the Director.

(k) *Signs and labels.* (1) The employer shall post signs in regulated areas bearing the following legend:

DANGER

BENZENE

CANCER HAZARD

FLAMMABLE—NO SMOKING

AUTHORIZED PERSONNEL ONLY

RESPIRATOR REQUIRED

(2) The employer shall assure that caution labels are affixed to all containers of benzene and of products containing any amount of benzene, except:

(i) Pipelines, and

(ii) Transport vessels or vehicles carrying benzene or benzene products in sealed intact containers.

(3) The employer shall assure that the caution labels remain affixed when the benzene or products containing benzene are sold, distributed or otherwise leave the employer's workplace.

(4) The caution labels required by paragraph (k)(2) of this section shall be readily visible and legible. The labels shall bear the following legend:

CAUTION

CONTAINS BENZENE

CANCER HAZARD

(5) The employer shall assure that no statement which contradicts or detracts from the information required by paragraphs (k)(1) and (k)(4) of this section appears on or near any required sign or label.

(l) *Recordkeeping.*—(1) *Exposure measurements.* (i) The employer shall establish and maintain an accurate record of all measurements required by paragraph (e) of this section.

(ii) This record shall include:

(*a*) The dates, number, duration, and results of each of the samples taken, including a description of the procedure used to determine representative employee exposures;

(*b*) A description of the sampling and analytical methods used;

(*c*) Type of respiratory protective devices worn, if any; and

(*d*) Name, social security number, and job classification of the employee monitored and all other employees whose exposure the measurement is intended to represent.

(iii) The employer shall maintain this record for at least 40 years or the duration of employment plus 20 years, whichever is longer.

(2) *Medical surveillance.* (i) The employer shall establish and maintain an accurate record for each employee subject

to medical surveillance required by paragraph (i) of this section.

(ii) This record shall include:

(*a*) The name, and social security number of the employee;

(*b*) A copy of the physicians' written opinions, including results of medical examinations and all tests, opinions and recommendations;

(*c*) The peripheral blood smear slides of the initial test, the most recent test, and any test demonstrating hematological abnormalities related to benzene exposure;

(*d*) Any employee medical complaints related to exposure to benzene;

(*e*) A copy of this standard and its appendices, except that the employer may keep one copy of the standard and its appendices for all employees provided that he references the standard and its appendices in the medical surveillance record of each employee;

(*f*) A copy of the information provided to the physician as required by paragraphs (i)(3)(ii) through (i)(3)(v) of this section; and

(*g*) A copy of the employee's medical and work history related to exposure to benzene or any other hematologic toxins.

(iii) The employer shall maintain this record for at least 40 years or for the duration of employment plus 20 years, whichever is longer.

(3) *Availability.* (i) The employer shall assure that all records required to be maintained by this section shall be made available upon request to the Assistant Secretary and the Director for examination and copying.

(ii) The employer shall assure that employee exposure measurement records as required by this section be made available for examination and copying to affected employees or their designated representatives.

(iii) The employer shall assure that former employees and the former employees' designated representatives have access to such records as will indicate the former employee's own exposure to benzene.

(iv) The employer shall assure that employee medical records required to be maintained by this section be made available upon request for examination and copying to a physician or other individual designated by the affected employee or former employee.

(4) *Transfer of records.* (i) When the employer ceases to do business, the successor employer shall receive and retain all records required to be maintained by paragraph (l) of this section for the prescribed period.

(ii) When the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, the employer shall transmit these records by mail to the Director.

(iii) At the expiration of the retention period for the records required to be maintained under paragraph (l) of this section, the employer shall transmit these records by mail to the Director.

(m) *Observation of monitoring.*—(1) *Employee observation.* The employer shall provide affected employees, or their designated representatives, an opportunity to observe any measuring or monitoring of employee exposure to benzene conducted pursuant to paragraph (e) of this section.

(2) *Observation procedures.* (i) When observation of the measuring or monitoring of employee exposure to benzene requires entry into areas where the use of protective clothing and equipment or respirators is required, the employer

shall provide the observer with personal protective clothing and equipment or respirators required to be worn by employees working in the area, assure the use of such clothing and equipment or respirators, and require the observer to comply with all other applicable safety and health procedures.

(ii) Without interfering with the measurement, observers shall be entitled to:

(*a*) Receive an explanation of the measurement procedures;

(*b*) Observe all steps related to the measurement of airborne concentrations of benzene performed at the place of exposure; and

(*c*) Record the results obtained.

(n) *Appendices.* The information contained in the appendices is not intended, by itself, to create any additional obligations not otherwise imposed or to detract from any existing obligations.

APPENDIX A

Substance Safety Data Sheet, Benzene

I. SUBSTANCE IDENTIFICATION

A. *Substance.* Benzene.

B. *Permissible Exposure:* Except as to the use as fuels of gasoline, motor fuels and other fuels subsequent to discharge from bulk terminals.

1. *Airborne.* 1 part of benzene vapor per million parts of air (1 ppm); time-weighted average (TWA) for an 8-hour workday for a 40-hour week, with a 15 minute ceiling concentration of 5 ppm.

2. *Dermal.* Eye contact and skin contact with liquid benzene shall be prohibited.

C. *Appearance and odor.* Benzene is a clear, colorless liquid with a pleasant, sweet odor. The odor of benzene does not provide adequate warning of its hazard.

II. HEALTH HAZARD DATA

A. *Ways in which the benzene affects your health.* Benzene can affect your health if you inhale it, or if it comes in contact with your skin or eyes. Benzene is also harmful if you happen to swallow it.

B. *Effects of overexposure.* 1. Short-term (acute) overexposure: If you are overexposed to high concentrations of benzene, well above the levels where its odors are first recognizable, you may feel breathless, irritable, euphoric, or giddy; you may experience irritation in eyes, nose, and respiratory tract. You may develop a headache, feel dizzy, nauseous, or experience unsteadiness in walking. Severe exposures may lead to convulsions.

2. *Long-term (chronic) exposure.* Repeated or prolonged exposure to benzene, even at relatively low concentrations, may result in various blood disorders, ranging from anemia to leukemia, an irreversible, fatal disease. Many blood disorders associated with benzene exposure may occur without physical symptoms.

III. PROTECTIVE CLOTHING AND EQUIPMENT

A. *Respirators.* Respirators are required for those operations in which engineering controls or work practice controls are not feasible to reduce exposure to the permissible level. If respirators are worn, they must have a National Institute for Occupational Safety and Health (NIOSH) seal of approval, and cartridges or canisters must be replaced before the end of their service life, or the end of the shift, whichever occurs first. If you experience difficulty breathing while wearing a respirator, tell your employer.

B. *Protective Clothing.* You must wear impervious protective clothing (such as boots, gloves, sleeves, aprons, etc.) over any parts of your body that could be exposed to liquid benzene.

C. *Eye and Face Protection.* You must wear splash proof safety goggles if it is possible that benzene may get into your eyes. In addition, you must wear a face shield if your face could be splashed with benzene liquid.

IV. EMERGENCY AND FIRST AID PROCEDURES

A. *Eye and face exposure.* If benzene is splashed in your eyes, wash it out immediately with large amounts of water. Call a doctor as soon as possible.

B. *Skin exposure.* If benzene is spilled on your clothing or skin, remove the contaminated clothing and wash the exposed skin with large amounts of water and soap immediately. Wash contaminated clothing before you wear it again.

C. *Breathing.* If you or any other person breathes in large amounts of benzene, get the exposed person to fresh air at once. Apply artificial respiration if breathing has stopped. Call for medical assistance or a doctor as soon as possible.

D. *Swallowing.* If benzene has been swallowed and the patient is conscious, do not induce vomiting. Call for medical assistance or a doctor immediately.

V. MEDICAL REQUIREMENTS

If you are exposed to benzene at a concentration at or above 0.5 ppm on an 8-hour time-weighted average, your employer is required to provide a medical history and laboratory tests within 30 days of the effective date of this standard and semiannually thereafter if you are continually exposed at or above 0.5 ppm. These tests shall be provided without cost to you. In addition, if you are accidentally exposed to benzene (either by ingestion, inhalation, or

skin/eye contact) under conditions known or suspected to be toxic exposure to benzene, your employer is required to make special tests available to you.

VI. OBSERVATION OF MONITORING

Your employer is required to perform measurements that are representative of your exposure to benzene and you or your designated representative are entitled to observe the monitoring procedure. You are entitled to receive an explanation of the measurement procedure, observe the steps taken in the measurement procedure, and to record the results obtained. When the monitoring procedure is taking place in an area where respirators or personal protective clothing and equipment are required to be worn, you or your representative must also be provided with, and must wear the protective clothing and equipment.

VII. ACCESS TO RECORDS

You or your representative are entitled to see the records of measurements of your exposure to benzene upon request to your employer. Your medical examination records can be furnished to your physician or designated representative upon request to your employer.

VIII. PRECAUTIONS FOR SAFE USE, HANDLING AND STORAGE

Benzene liquid is highly flammable. It should be stored in tightly closed containers in a cool, well ventilated area. Benzene vapor may form explosive mixtures in air. All sources of ignition must be controlled. Use nonsparking tools when opening or closing benzene containers. Ground or bond metal benzene containers. Fire extinquishers, where provided, must be readily available. Know where they are located and how to operate them. Smoking is prohibited in areas where benzene is used or stored. Ask your supervisor where benzene is used in your work area and for additional plant safety rules.

APPENDIX B

SUBSTANCE TECHNICAL GUIDELINES, BENZENE

I. PHYSICAL AND CHEMICAL DATA

A. *Substance identification.*

1. Synonyms: Benzol, benzole, coal naptha, cyclohexatriene, phene, phenyl hydride, pyrobenzol. (Benzine, petroleum benzine, and benzine do not contain benzene.)

2. Formula: C_6H_6 (CAS Registry Number: 000071432).

B. *Physical data.*

1. Boiling Point (760 mm Hg): 80.1C (176F)

2. Specific Gravity (water = 1): 0.879

3. Vapor Density (air = 1): 2.7

4. Melting Point: 5.5C (42F)

5. Vapor Pressure at 20C (68F): 75 mm Hg

6. Solubility in Water: .06%

7. Evaporation Rate (ether = 1): 2.8

8. Appearance and Odor: Clear, colorless liquid with a distinctive sweet odor.

II. FIRE, EXPLOSION, AND REACTIVITY HAZARD DATA

A. *Fire.*

1. Flash Point (closed cup): −11C (12F)

2. Autoignition Temperature: 580C (1076F)

3. Flammable Limits in Air, % by Volume: Lower 1.3%, Upper: 7.5%

4. Extinguishing Media: Carbon dioxide, dry chemical, or foam.

5. Special Fire-Fighting Procedures: Do not use solid stream of water, since stream will scatter and spread fire.

Water spray can be used to keep fire exposed containers cool.

6. Unusual fire and explosion hazards: Benzene is a flammable liquid. Its vapors can form explosive mixtures. All ignition sources must be controlled when benzene is used, handled, or stored. Where liquid or vapor may be released, such areas shall be considered as hazardous locations. Benzene vapors are heavier than air; thus the vapors may travel along the ground and be ignited by open flames or sparks at locations remote from the site at which benzene is handled.

7. Benzene is classified as a *1 B flammable liquid* for the purpose of conforming to the requirements of 29 CFR 1910.106. A concentration exceeding *3250 ppm* is considered a potential fire explosion hazard. Locations where benzene may be present in quantities sufficient to produce explosive or ignitable mixtures are considered *Class I Group D* for the purposes of conforming to the requirement of 29 CFR 1910.309.

B. *Reactivity.*

1. Conditions contributing to instability: Heat.

2. Incompatibility: Heat and oxidizing materials.

3. Hazardous decomposition products: Toxic gases and vapors (such as carbon monoxide).

III. SPILL AND LEAK PROCEDURES

A. *Steps to be taken if the material is released or spilled.* As much benzene as possible should be absorbed with suitable materials, such as dry sand or earth. That remaining must be flushed with large amounts of water. Do not flush benzene into a confined space, such as a sewer, because of explosion danger. Remove all ignition sources. Ventilate enclosed places.

B. *Waste disposal method.* Disposal methods must conform to other jurisdictional regulations. If allowed, benzene may be disposed of: (a) Absorbing it in dry sand or earth and disposing in a sanitary land fill; (b) if small quantities, by removing it to a safe location from buildings or other combustible sources, pouring it in dry sand or earth and cautiously igniting it: (c) if large quantities, by atomizing it in a suitable combustion chamber.

IV. MONITORING AND MEASUREMENT PROCEDURES

A. *Normal monitoring program.* Measurements taken from the purpose of determining employee exposure are best taken so that the representative average 8-hour exposure may be determined from a single 8-hour sample or two (2) 4-hour samples. Short-time interval samples (or grab samples) may also be used to determine average exposure level if a minimum of five measurements are taken in a random manner over the 8-hour work shift. Random sampling means that any portion of the work shift has the same chance of being sampled as any other. The arithmetic average of all such random samples taken on one work shift is an estimate of an employee's average level of exposure for that work shift. Air samples should be taken in the employee's breathing zone (air that would nearly represent that inhaled by the employee). Sampling must be performed by gas absorption tubes or alternative methods meeting the requirements of the standard with subsequent chemical analysis, by gas chromatography. Methods meeting the prescribed accuracy and precision and requirements are available in the "NIOSH manual of Analytical Methods."

V. MISCELLANEOUS PRECAUTIONS

A. High exposures to benzene can occur when transferring the liquid from one container to another. Such operations should be well ventilated and good work practices must be established to avoid spills.

B. Use non-sparking tools to open benzene containers which are effectively grounded and bonded prior to opening and pouring.

C. Employers must advise employees of all plant areas and operations where exposure to benzene could occur. Common operations in which high exposures to benzene may be encountered are: the primary production and utilization of benzene, and transfer of benzene.

APPENDIX C

Medical Surveillance Guidelines for Benzene

I. ROUTE OF ENTRY

Inhalation; possible skin absorption.

II. TOXICOLOGY

Benzene is primarily an inhalation hazard. Systemic absorption may cause depression of the hematopoietic system and leukemia. Inhalation of high concentrations can affect the central nervous system function. Aspiration of small amounts of liquid benzene immediately causes pulmonary edema and hemorrhage of pulmonary tissue. The extent of absorption through the skin is unknown. However, absorption may be accelerated in the case of injured skin, and benzene may be more readily absorbed if it is present in a mixture or as a contaminant in solvents which are readily absorbed. Defatting action of benzene may produce primary irritation upon repeated or prolonged contact with the skin. High concentrations are irritating to the mucuous membranes of the eyes, nose, and respiratory tract.

III. SIGNS AND SYMPTOMS

It is not clear to what extent benzene is absorbed through the skin, however, direct contact may cause erythema or blistering. Repeated or prolonged contact may result in

drying, scaling dermatitis, or precipitate development of secondary skin infections. Local effects of benzene vapor or liquid on the eye are slight. Only at very high concentrations is there any smarting sensation in the eye. Inhalation of high concentrations of benzene may have an initial stimulatory effect on the central nervous system characterized by exhiliration, nervous excitation, and/or giddiness, followed by a period of depression, drowsiness, fatigue, or vertigo. There may be sensation of tightness in the chest accompanied by breathlessness and ultimately the victim may lose consciousness. Convulsions and tremors occur frequently, and death may follow from respiratory paralysis or circulatory collapse in a few minutes to several hours following severe exposures.

The insidious effect on the blood-forming system of prolonged exposure to small quantities of benzene vapor is of extreme importance. The hematopoietic system is the chief target for benzene's toxic effects which are manifested by alterations in the levels of formed elements in the peripheral blood. These effects have been noted to occur at concentrations of benzene which may not cause irritation of mucous membranes, or any unpleasant sensory effects. Early signs and symptoms of benzene morbidity are varied and often not overtly apparent and not specific for benzene exposure. Subjective complaints of headache, dizziness, and loss of appetite may precede or follow clinical symptomology. Bleeding from the nose, gums, or mucous membranes and the development of purpuric spots may occur as the condition progresses. Rapid pulse and low blood pressure in addition to a physical appearance of anemia may accompany a subjective complaint of shortness of breath. Clinical evidence of leukopenia, anemia, and thrombocytopenia, singly or in combination, have been frequently reported.

Bone marrow may appear normal, aplastic, or hyperplastic and may not in all situations correlate with peripheral blood forming tissues. There are great variations in

the susceptibility to benzene morbidity which prohibits the identification of "typical" blood picture. The onset of effects of prolonged benzene exposure may be significantly delayed after the actual exposure has ceased.

IV. TREATMENT OF ACUTE TOXIC EFFECTS

Remove from exposure immediately, give oxygen or artificial resuscitation if indicated. Flush eyes and wash contaminated skin. Symptoms of non-specific nervous disturbances may persist following severe exposures. Recovery from mild exposures is usually rapid and complete.

V. SURVEILLANCE AND PREVENTIVE CONSIDERATIONS

A. GENERAL

The principal effects of benzene exposure forming the basis for this regulation are alterations of the hematopoietic system as reflected by changes in the peripheral blood and leukemia. Consequently, the medical surveillance protocol is designed to observe on a regular basis, blood indices for early signs of these effects.

Tests must be performed frequently enough to discover individuals who may be unusually sensitive and likely to develop marrow abnormalities, to monitor those who experience accidental overexposure and to provide early detection of delayed evidence of toxicity.

All workers who are or will be exposed to 0.5 parts per million (ppm) or greater benzene as an eight-hour time-weighted average are to be given the opportunity for a medical examination. Initial examinations are to be provided within 30 days of the effective date of this standard or at the time of initial assignment and interval examinations semiannually thereafter. There are special provisions for medical tests in the event of hematological abnormalities or for emergency situations.

F. HEMATOLOGY GUIDELINES

The following information excerpted from the analysis of Dr. Jandl, Chief of Hematology, Harvard School of Medicine, may be useful to physicians in conducting the medical surveillance program.

"A minimum battery of tests is to be performed by strictly standardized methods in the circumstances described above.

1. Red cell, white cell, and platelet counts must be performed using an automated (Coulter) counter. The normal range for the red cell count is approximately 4.4 to 6.0 million cells/mm^3, the values for women being about 0.4 million cells lower than for men. A decline from a normal to a subnormal value, or a rise to a supra-normal value, are indicative of potential toxicity, particularly should there be a decline. The normal total white blood count is approximately 6,200 plus or minus 2,000/mm^3. For cigarette smokers and white count will be higher, the upper range of "normal" being approximately 1,000 cells higher than 8,200. Either a decline from normal to subnormal or a rise from normal to supra-normal, should be regarded as a potential indication of benzene toxicity. The normal platelet count is 250,000 with a range of 140,000 to (at most) 400,000/mm^3. A decline to below 140,000 or a rise to above 400,000 should be regarded as possible evidence of benzene toxicity.

The reticulocyte count is performed by technical assistants using a cover-slip smear (see below). In my opinion, the preferred technique for this purpose is the so-called "dry-method" employing brilliant cresyl blue (BCB) for staining the filaments of reticulum within red cell, and counter-staining with Wright's stain. The extreme range of normal for reticulocytes is 0.4 to 1.5 percent of the red cells, the usual range being 0.5 to 1.2 percent of the red cells, but the typical value is in the range of 0.8 to 1.0 percent. There is an advantage of using the BCB reticulocyte stain-

ing technique (followed by counter-staining with Wright's stain) in that visible evidence (i.e., the stained, mounted reticulocyte smears) may be stored, and if kept filed in the dark may later be retrieved for reexamination and comparisons. A decline in reticulocytes to levels of less than 0.4 percent is to be regarded as possible evidence (unless another specific cause is found) of benzene toxicity requiring accelerated surveillance. An increase in reticulocyte levels to above 1.5 percent may also be consistent with (but is not as characteristic of) benzene toxicity.

2. The single most important routine surveillance test is an expert technician's careful examination of the peripheral blood smear. As with the reticulocyte count, the smear should be with fresh uncoagulated blood obtained from a needle tip following venipuncture or from a drop of earlobe blood (capillary blood). If necessary, the smear may under certain limited conditions be made from a blood sample anticoagulated with EDTA (but never with oxalate or heparin). When the smear is to be prepared from a specimen of venous blood which has been collected by a commercial Vacutainer[R] type tube containing neutral EDTA, the smear should be made as soon as possible after the venesection. A delay of up to 12 hours is permissible between the drawing of the blood specimen into EDTA and the preparation of the smear if the blood is stored at refrigerator (not freezing) temperature. As with the reticulocyte preparations, the smear should be made on cover slips only. Under no circumstances should peripheral blood (or bone marrow aspirate) intended for examination be smeared on microscope slides, a technique which produces artifacts in blood cells and distorts the white cell differential count by severely maldistributing them. Dry blood smears should be stained with Wright's stain which should be filtered at least weekly to remove precipated dye (saturated completely by methylene blue-eosinate derivates).

3. The minimum mandatory observations to be made from the smear and a discussion of their significance now follows. The observations are four:

a. The differential white blood cell count.

b. Description of abnormalities in the appearance of red cells.

c. Description of any abnormalities in the platelets.

d. A careful search must be made by the technician throughout the better areas of every blood smear for immature white cells such as band forms (in more than normal proportion), any number of metamyelocytes, myelocytes. Any nucleated or multinucleated red blood cells should be reported. Very large "giant" platelets of fragments of megakaryocytes must be recognized. Should only a single one of these abnormalities be found, it should be reported.

An increase in the proportion of band forms among the neutrophilic granulocytes is an abnormality deserving special mention for it represents a very early change which should be considered as an early warning of benzene toxicity in the absence of other causative factors (most commonly infection). Likewise, the appearance of metamyelocytes in the absence of other probable cause is to be considered a possible indication of benzene-induced injury.

An upward trend in the number of basophils, which normally do not exceed about 2.0 percent of the total white cells, is to be regarded as possible evidence of benzene toxicity. A rise in the eosinophil count is less specific but also may be suspicious of toxicity if it rises above 6.0 percent of the total white count.

The normal range of monocytes is from 2.0 to 8.0 percent of the total white count an average of about 5.0 percent. About 20 percent of individuals reported to have mild but persisting abnormalities caused by exposure to benzene show a persisting monocytosis which is sometimes striking.

The findings of a monocyte count which persists at more than 10 to 12 percent of the normal white cell count (when the total count is normal) or persistance of an absolute monocyte count in excess 800/mm^3 should be regarded as a possible sign of benzene-induced injury.

A less frequent but more serious indication of benzene-induced injury to the bone marrow is the findings in the peripheral blood of the so-called "pseudo" (or acquired) Pelger-Huet anomaly. In this anomaly many, or sometimes the majority, of the neutrophilic granulocytes possess two round nuclear segments—less often one or three round segments—rather than three normally elongated segments. When this anomaly is not hereditary, it is often but not invariably predictive of subsequent leukemia. However, only about two percent of patients who ultimately develop acute myelogenous leukemia show the acquired Pelger-Huet anomaly.

An uncommon but ominous sign, one which cannot be detected from the smear, but can be suspected easily by a "sucrose water test" or peripheral blood, is transient paroxysmal nocturnalhemoglobinuria (PNH), which may first occur insidiously during a period of established aplastic anemia and maybe followed within one to a few years by the appearance of rapidly fatal acute myelogenous leukemia. Clinical detection of PHH, which occurs in perhaps only one or two percent of those destined to have acute myelogenous leukemia, may be difficult; if the presumptive "sucrose water test" for it is positive, the technician may perform the somewhat more definitive Ham test, also known as the acid-serum hemolysis test.

e. Individuals documented to have developed acute myelogenous leukemia years after initial exposure to benzene, have (see above) progressed through preliminary phases of hematologic abnormality. In many instances pancytopenia(i.e., a lowering in the counts of all circulating blood cells of bone marrow origin—but not to the extent implied

by the term "aplastic anemia") preceded leukemia for many years. Seldom does relative scarcity of a single type blood cell (or of platelets) represent a harbinger of imminent acute leukemia. However, the finding of two or more cytopenias, or of pancytopenia, must be regarded as highly suspicious of more advance although still reversible, benzene toxicity. When "pancytopenia" develops and becomes associated with the appearance of immature cells (myelocytes, myeloblasts, erythorblasts, etc.), with abnormal cells (pseudo Pelger-Huet anomaly, atypical nuclear heterochromatin, etc.), or with inappropriate elevations of monocytes, basophils, or eosinsophils, the findings must be regarded as evidence of benzene overexposure unless proved otherwise. These and other aggregates of alterations are frequently termed "preleukemia," a term whose meaning is good when used retrospectively, but less good when used prospectively where it has only inferential value. Many severely aplastic patients manifested the ominous finding of 5-10 percent myeloblasts in the marrow, occasional myeloblasts and myelocytes in the blood and 20-30% monocytes; these represented the beginning of recovery rather than the early stage of overt AML. Thus, a considerable proportion of "preleukemias" in benzene poisioning fail to progress to leukemia. Indeed, some have been observed to revert to normal after withdrawal of the afflicted person from toxic exposure. Nonetheless, the chance that "preleukemic" (changes in general) will evolve to leukemia is considerable: at least 20 to 40 percent of persons (only a few of whom were benzene-exposed) with these blood changes develop acute myelogenous leukemia. Certain tests may substantiate the person's prospects for progression or regression. One such test would be an examination of patient's bone marrow. But the decision to perform a bone marrow aspiration or needle biopsy is one that should be made by the hematologist. The findings to be sought there would be: hypoplasia or aplasia; an excess of immature forms; vacuolation in erythroblasts and myelocytes—a phenomenon

induced by many toxins apart from benzene, including chloramphenicol and alcohol; and by infections.

The findings of basophilic stippling in circulating red blood cells (usually found in 1 to 5% of red cell during marrow injury), and detection in the bone marrow of what are termed "ringed sideroblasts" must be taken seriously, as they have been noted in recent years to be frequent premonitory signs of subsequent acute leukemia.

In several recent reports dealing with relatively few patients, peroxidase-staining of circulating or marrow neutrophil granules, employing benzidine dihydrochloride, has revealed as a "preleukemic" finding the disappearance of, or dimunition in, perosidase in a sizable proportion of the granulocytes. Granulocyte granules are normally strongly peroxidase positive. A steady decline in leukocyte alkaline phosphatase is also suggestive of early acute leukemia. Exposure to benzene commonly causes an early rise in serum iron, often but not always associated with a fall in the reticulocyte count. Thus serial measurements of serum iron levels provide a means of determining whether or not there is a trend representing sustained suppress of erythropoiesis.

Measurement of serum iron, determination of peroxidase and of alkaline phosphatase activity in peripheral granulocytes can be performed by technical assistants.

(Secs. 4, 6, 8, 84 Stat. 1593 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order 8-76 (41 FR 25059); 29 CFR part 1911.)

[FR Doc. 78-3417 Filed 2-3-78; 1:12 pm]

APPENDIX C

TITLE 29—LABOR

CHAPTER XVII

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, DEPARTMENT OF LABOR

PART 1910

OCCUPATIONAL SAFETY AND HEALTH STANDARDS
OCCUPATIONAL EXPOSURE TO BENZENE

AGENCY: The Occupational Safety and Health Administration, Department of Labor.

ACTION: Permanent standard for the regulation of benzene.

SUMMARY: This standard is based on a determination by the Occupational Safety and Health Administration (OSHA) that the available scientific evidence establishes that employee exposure to benzene presents a cancer hazard—specifically, the hazard of developing leukemia. Therefore, in accordance with OSHA's regulatory approach to the control of employee exposure to carcinogens, this standard limits employee exposure to benzene to the lowest feasible level, in this case 1 part benzene per million parts of air (1 ppm) as an 8 hour time—weighted average concentration, with a ceiling level of 5 ppm for any 15 minute period during the 8 hour day. The standard also prescribes limits on eye and skin contact with benzene.

The standard provides for the measurement of employee exposure, engineering controls, work practices, personal protective clothing and equipment, signs and labels, employee training, medical surveillance and recordkeeping.

EFFECTIVE DATE: March 13, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. Gail Brinkerhoff, Office of Compliance Programs, OSHA, Third Street and Constitution Avenue N.W., Room N3112, Washington, D.C. 20210, telephone 202-523-8034.

SUPPLEMENTARY INFORMATION: This permanent Occupational Safety and Health standard is issued pursuant to sections 6(b), 6(c) and 8(c) of the Occupational Safety and Health Act of 1970 (the Act) (84 Stat. 1593, 1596, 1599; 29 U.S.C. 655, 657), the Secretary of Labor's Order No. 8-76 (41 FR 25059) and 29 CFR Part 1911. The new standard on occupational exposure to benzene which appears at 29 CFR 1910.1028, applies to all employment in all industries covered by the Act. For reasons set out below, the standard does not apply to the distribution or use of gasoline and other fuels, used as fuels, subsequent to discharge from bulk terminals. Moreover, the standard applies labelling and training requirements only to sealed, intact containers of benzene.

This document also amends Table z-2 of 29 CFR 1910.1000 by adding a footnote which provides that benzene exposures not covered by the new § 1910.1028 are still covered by the exposure level and other requirements of § 1910.1000. Pursuant to section 4(b)(2) of the Act, OSHA has determined that this standard is more effective than corresponding standards now applicable to the maritime and construction industries and currently contained in Subpart B of Part 1910, and Parts 1915, 1916, 1917, 1918 and 1926 of Title 29, Code of Federal Regulations. Therefore, those corresponding standards are superseded by the new standards in §1910. 1028. A new paragraph (c) is added to § 1910.19 to clarify the applicability of this new benzene standard to the construction and maritime industries.

I. Background

Benzene (C_6H_6) is a clear, colorless, non-corrosive, highly flammable liquid with a strong, rather pleasant odor. Benzene's low boiling point and high vapor pressure cause it to evaporate rapidly under ordinary atmospheric conditions, giving off vapors nearly three times heavier than air.

Benzene is produced primarily by the petrochemical and petroleum refining industries by a process called catalytic reformation, which converts certain lower octane hydrocarbons into higher octane aromatics. These two industries are responsible for 94 percent of the total U.S. production of benzene. Recovery through catalytic reformation, including the benzene formed from the hydroalkylation of toluene, accounts for almost 80 percent of the total quantity produced. Recovery of coal-derived benzene, primarily as a by-product of the coking process in steel mills, was once the major source of benzene. Today, however, it accounts for only 6 percent of the total U.S. production.

The production of benzene is rapidly expanding with approximately 11 billion pounds produced in 1976. Only eleven other chemicals and only one other hydrocarbon (ethylene) are produced in greater tonnage in the U.S. Approximately 86 percent of this benzene is used chiefly as an intermediate in the production of other organic chemicals, including styrene, phenol, and cyclohexane. The remaining amount is used primarily in the manufacture of detergents, pesticides, solvents and paint removers. Benzene is also present as a component of motor fuels, averaging less than 2 percent in gasoline.

The first major industrial use of benzene, however, was as a solvent in the rubber industry just preceding World War I. During World War I, benzene production was stimulated greatly by the demand for and resulting production of toluene in the manufacture of explosives. The large quantities of benzene which were produced, resulted in its more

widespread use as a starting point for the manufacture of various organic compounds. This situation led to greatly increased uses of benzene as a solvent in the artificial leather, rubber goods, and rotogravure industries.

Industries and processes currently using benzene include the chemical, printing, lithograph, rubber cements, rubber fabricating, paint, varnish, stain removers, adhesives, and petroleum industries. Benzene is also used extensively in chemical laboratories as a solvent and as a reactant in numerous chemical applications. Where benzene is produced and used in large amounts it is generally used in enclosed systems, although exposures can occur during liquid transfer operations, from equipment leakage and carryover losses, and in maintenance operations.

II. History of Regulation

Benzene has been recognized as a toxic substance capable of causing acute or chronic effects since 1900. In 1927, on the basis of extensive examination of exposed workmen and animal inhalation data, Winslow recommended an exposure limit of 100 ppm for benzene (Ex. 156-3, Annex D).[1] In 1934, partially as a result of the fact that benzene toxicity in the shoe leather industries was a serious problem in that state, the Massachusetts Department of Labor and Industries established a Division of Occupational Hygiene (Ex. 156-3, p. 2). Relying on reports by Bowditch, Hunter, Mallory and Elkins of cases of benzene poisoning occurring at concentrations below 100 ppm, the Massachusetts Division of Occupational Hygiene reduced the maximum acceptable limit (MAC) to 75 ppm (Ex. 156-3, pp. 6-7). In the 1940's, as a result of blood abnormalities and one death among leather workers exposed to benzene concentrations ranging from 40 to 80 ppm, Massachusetts lowered the permissable limit of benzene exposure to 35 ppm (Elkins Ex. p. 7).

[1] The exhibit numbers used in this document refer to the certified exhibit list of the benzene rulemaking proceeding. The first number designates the particular exhibit on that list. Where the exhibit contains more than one item, the second number references the particular item of the exhibit. The designation "PC" refers to post-hearing comments in Exhibit 217. The designation "Tr" refers to the transcript of the benzene hearing and indicates the pages of that transcript which are referenced.

All references in this document are intended to provide examples of record support for the information stated.

The American Conference of Governmental Industrial Hygienists (ACGIH) recommended in 1946 a threshold limit value (TLV) for benzene exposure of 100 ppm. This TLV was reduced in 1947 to 50 ppm. In 1948, following Massachusetts' lead, ACGIH adopted a TLV of 35 ppm. In 1963, a TLV of 25 ppm was proposed by the ACGIH. The effects of benzene noted by ACGIH at this time were blood changes, aplastic anemia and other blood dyscrasias. No mention was made of any association of leukemia with benzene exposure (Ex. 191). It was not until 1974 that the ACGIH adopted the TLV of 10 ppm which had sometime earlier been recommended by the American National Standards Institute (Ex. 156-3, p. 7).

The present OSHA standard for benzene (29 CFR Part 1910.1000, Table Z-2) was adopted in 1971 from the Z 37.4—1969 consensus standard of the American National Standards Institute (ANSI). The OSHA standard was adopted without rulemaking under the authority of section 6(a) of the Act. It prescribes, as the ANSI standard, an 8-hour TWA of 10 ppm with an acceptable ceiling concentration of 25 ppm and, in addition, allows excursions above the ceiling to a maximum peak concentration not to exceed 50 ppm for more than 10 minutes in any 8-hour work period. Neither the ANSI standard nor the resultant OSHA standard was based on the possible leukemogenic effects of exposure to benzene.

In 1974, pursuant to section 22(d) of the Act, the Director of NIOSH submitted to the Secretary of Labor a criteria

document concerning occupational exposure to benzene which stated that "the possibility that benzene can induce leukemia cannot be dismissed." (Ex. 32A, p. 1). However, NIOSH recommended retention of the existing permissible exposure limit to 10 ppm and ceiling concentration of 25 ppm as measured over a 10 minute period. This recommendation was not based on benzene's potential leukemia hazard.

In a letter to the Secretary of Labor, dated April 23, 1976, the United Rubber, Cork, Linoleum, and Plastic Workers of America urged that an emergency temporary standard regulating occupational exposure to benzene be issued (Ex. 2-42). This request was denied on May 18, 1976 by then Secretary of Labor, William J. Usery (Ex. 2-43).

Also in 1976, the National Academy of Sciences under contract with the United States Environmental Protection Agency, reviewed the literature concerning health effects of benzene exposure (Ex. 2-4). The Academy concluded that benzene must be considered a suspect leukemogen.

In August 1976, NIOSH submitted to OSHA an updated criteria document which revised its earlier assessment of 1974 (Ex. 2-6). On the basis of a review of old studies and new data, NIOSH concluded in that document that benzene was a leukemogen. This report further pointed out that "it is apparent from the literature that benzene leukemia continues to be reported." NIOSH, therefore, recommended that since no safe level for benzene exposure could be established that, "no worker be exposed to benzene in excess of 1 ppm in air." Following publication of the updated criteria document, the Director of NIOSH recommended to the Assistant Secretary of Labor, by letter dated October 27, 1976, that OSHA publish an emergency temporary standard for benzene establishing the exposure level at 1 ppm (Ex. 2-6).

Based on the information supplied by NIOSH, OSHA issued on January 14, 1977, voluntary "Guidelines for Control of Occupational Exposure to Benzene," recommending that exposure to benzene in air not exceed an 8-hour time-weighted average to 1 ppm in any 8-hour shift of a 40-hour week (Ex. 2-44).

In January 1977, NIOSH informed OSHA that workplace environments had been found in St. Mary's and Akron, Ohio where a sufficient number of employees had been exposed to benzene for a number of years to facilitate an epidemiological study of health risks (Ex. 2-45). The worksite was a manufacturing plant owned by Goodyear Tire and Rubber Company which utilized benzene at various stages in the production of pliofilm. The preliminary conclusions of the epidemiological study, which NIOSH conducted of the pliofilm workers, were transmitted to OSHA on April 15, 1977. In his letter of April 15, 1977, transmitting this report, the Director of NIOSH again urged that an emergency standard be issued (Ex. 2-7).

On May 3, 1977, the Assistant Secretary for OSHA issued an Emergency Temporary Standard for Occupational Exposure to Benzene (42 FR 22516), pursuant to sections 6(c) and 8(c) of the Act, Secretary of Labor's Order No. 8-76, and 29 CFR Part 1911. A correction document was published on May 10, 1977 (41 FR 23601), and an amendment to the emergency temporary standard as published on May 24, 1977 (42 CFR 26429). The evidence and findings supporting issuance of the emergency temporary standard and its amendment and a discussion of its provisions are set forth in the aforementioned *Federal Register* publications. The emergency temporary standard was to have been effective on May 21, 1977. However, as a result of challenges to that standard, filed both in the Court of Appeals for the District of Columbia (*Industrial Union, AFL-CIO* v. *Bingham,* No. 77-1395) and in the Court of Appeals for the Fifth Circuit (*API* v. *OSHA,* No. 77-1516), a temporary restrain-

ing order was issued by the Fifth Circuit on May 20, 1977, and the standard never officially went into effect.

On May 27, 1977, OSHA published a proposed permanent standard to control occupational exposure to benzene (42 FR 27452). The emergency temporary standard and its preamble, which the new proposal supplemented, were incorporated in that proposal. The *Federal Register* document setting forth the proposal also contained a notice of hearing scheduling an informal public hearing to be held pursuant to section 6(b)(3) of the Act, and requesting the submission of written comments, data, views and arguments on all the issues raised by the proposed permanent standard and the emergency temporary standard. Subsequently, on June 24, 1977 (42 FR 32263), OSHA excluded from the scope of the benzene hearing and from the final permanent standard those activities related to the storage, transportation, distribution, dispensing and sale of gasoline as a fuel subsequent to its discharge from bulk terminals. OSHA explained in that notice its intention to assess the regulatory action to be taken to protect workers involved in these activities after conclusion of the deliberations of a joint EPA-NIOSH-OSHA Task Force.

The public hearings on the benzene proposal were held July 19 through August 10, 1977. A total of 95 individuals appeared at these hearings as witnesses. Among the witnesses were employers and employer associations from a variety of industries: petroleum refining, petrochemical, oil and gas production, aviation fueling; and coke ovens and coke by-products. In addition, representatives of the affected workforce, including a number of employees who have been exposed to benzene, unions, government agencies, public interest groups and other interested parties appeared. Furthermore, comments were received from representatives of other industries, such as analytical and research laboratories, paint manufacturing, construction, maritime, and rubber manufacturing and from users of

pure benzene as well as users of benzene contaminated solvents. Public participation was representative of a large segment of the benzene users. The verbatim transcript of the hearings, as well as the numerous comments, exhibits and briefs submitted to OSHA before, during and after the hearings, are part of this rulemaking record, along with other relevant documents. The hearing record was originally scheduled to close on August 20, 1977 but, at the request of industry participants, the record was kept open until September 2, 1977 for the submission of additional evidence and until September 27, 1977 for the submission of briefs, summaries and arguments.

In conjunction with the development of the proposed standard, OSHA prepared a draft environmental impact statement. The draft environmental statement was published in the *Federal Register* (42 FR 27455). On June 17, 1977, the Council on Environmental Quality published a notice of availability of the benzene draft environmental impact statement (Ex. 7). In addition to the 45-day comment period specified in 29 CFR 1999.4(g), the environmental impact of the proposed standard was also an issue for the benzene hearing as provided by 29 CFR 1999.4(h) and the notice of proposed rulemaking (42 FR 27452). A notice of availability of the final environmental impact statement for benzene was published on February 3, 1978 by EPA (43 FR 4674).

In addition to the draft environmental impact statement, OSHA prepared an economic and inflationary impact assessment of the proposed standard evaluating factors relevant under section 6(b) of the Act (29 U.S.C. 655(b)(5), Secretary of Labor's Order 15-75 (40 FR 54484) and Executive Orders Nos. 11821 (39 FR 41501) and 11949 (42 FR 1017). The notice of the proposed standard indicated that the economic impact of this proposal was to be considered at the hearing (42 FR 27452) and certified that the economic and inflationary impact of the proposed standard

has been carefully evaluated in accordance with Executive Orders 11821 and 11949.

This permanent benzene standard is based on a careful consideration of the entire record in this proceeding, including materials relied on in the emergency temporary standard, materials referenced in the proposal, and the record of the informal rulemaking hearing including the transcript, exhibits and pre-hearing and post-hearing written comments. Copies of the official list of hearing exhibits, comments, and notices of intent to appear at the hearing can be obtained from the Docket Office, Docket H-059, Room S6212, U.S. Department of Labor, 3rd Street and Constitution Avenue N.W., Washington, D.C. 20210.

III. Pertinent Legal Authority

The primary purpose of the Act is to assure, so far as possible, safe and healthful working conditions for every working man and woman. One means prescribed by Congress to achieve this goal is the authority vested in the Secretary of Labor to set mandatory safety and health standards.

Occupational safety and health standards provide notice of the requisite conduct or exposure level and provide a basis for assuring the existence of safe and healthful workplaces. The act provides that:

> The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of

> the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, and feasibility of the standards, and experience gained under this and other health and safety laws. (Section 6(b)(5).)

Sections 2(b)(5) and (6), (20), (21), (22), and (24) of the Act reflect Congress' recognition that conclusive medical or scientific evidence including causative factors, epidemiological studies or dose-response data may not exist for many toxic materials or harmful physical agents. Nevertheless, standards cannot be postponed because definitive medical or scientific evidence is not currently available. Indeed, standards need only be based on the best available evidence. The legislative history makes it clear that "it is not intended that the Secretary be paralyzed by debate surrounding diverse medical opinion." House Committee on Education and Labor, Report No. 91-1291, 91st Cong., 2d Session, p. 18 (1970). This Congressional judgment is supported by the courts which have reviewed standards promulgated under the Act. In sustaining the standard for occupational exposure to vinyl chloride (29 CFR 1910.1017), the U.S. Court of Appeals for the Second Circuit stated that "it remains the duty of the Secretary to act to protect the working man, and to act even in circumstances where existing methodology or research is deficient." "Society of the Plastics Industry Inc. v. Occupational Safety and Health Administration," 509 F.2d 1301 (C.A. 2 1975), cert. den. 95 S. Ct. 1998, 4 L.Ed.2d 482 (1975). A similar rationale was applied by the U.S. Court of Appeals for the District of Columbia Circuit in reviewing the standard for occupational exposure to asbestos (29 CFR 1910.1001). The Court stated that:

> Some of the questions involved in the promulgation of these standards are on the frontiers of scientific knowledge, and consequently as to them insufficient data is presently available to make a fully informed factual determination. Decision-making must in that

circumstance depend to a greater extent upon policy judgments and less upon purely factual judgments.

"Industrial Union Department, *AFL-CIO* v. *Hodgson*," 499 F.2d 467, 474 (C.A.D.C. 1974).

In setting standards, the Secretary is expressly required to consider the feasibility of the proposed standards. Senate Committee on Labor and Public Welfare, S. Rep. No. 91-1282, 91st Cong., 2d Sess., p. 58 (1970). Nevertheless, considerations of technological feasibility are not limited to devices already developed and in use. Standards may require improvements in existing technologies or require the development of new technology. "*Society of the Plastic Industry, Inc.* v. *Occupational Safety and Health Administration*," supra at 1309.

Where appropriate, the standards are required to include provisions for labels or other forms of warning to apprise employees of hazards, suitable protective equipment, control procedures, monitoring and measuring of employee exposure, employee access to the results of monitoring, and appropriate medical examination (section 6(b)(7)). Standards may also prescribe recordkeeping requirements where necessary or appropriate for enforcement of the Act or for developing information regarding occupational accidents and illnesses (section 8(c)). The permanent standard for benzene was developed on the basis of the above legal considerations.

IV. Health Effects

A. GENERAL

Inhalation is the primary route of entry of benzene in man. Benzene diffuses rapidly through the lungs and is quickly absorbed into the blood. The rate of absorption is greatest during the first five minutes and thereafter declines significantly. Benzene saturation of the circulating blood may reach as high as 70-80 percent saturation level within the first 30 minutes. However, relatively complete

saturation of the blood may not be attained for two to three days.

The benzene absorbed by the circulating blood is distributed throughout the body where, because of its liposolubility, it tends to accumulate in various body organs in proportion to their fat content.

Upon removal from benzene exposure, the concentration of benzene in the expired breath follows an exponential decay curve, reflecting removal of benzene from various body compartments. Elimination via this route for relatively high concentrations has been estimated to range from 12 to 50 percent of the total amount of benzene absorbed in humans.

Most of the absorbed benzene remaining ultimately is metabolized by enzymes contained in the liver to derivatives which are more water soluble thereby facilitating their removal by the kidneys. A first intermediate in the biotransformation of benzene is believed to be benzene epoxide, a highly reactive chemical. This is one of several candidates—others: Hydroquinone and catechol (Snyder Tr. 3229), suggested as the active agent responsible for benzene's hematotoxic effects. Phenol, and to a lesser extent, hydroquinone, pyrocatechol, and phenyl-mercapturic acid are the primary metabolites of benzene found in urine.

B. ACUTE EFFECTS

Exposures to high concentrations of benzene produce an almost immediate effect upon the central nervous system. Benzene concentrations near 20,000 ppm are fatal within minutes, with death occurring from acute circulatory failure or coma, with or without convulsions. Milder exposures produce a period of nervous excitation, euphoria, headache and nausea, followed by a period of depression which can result in cardiovascular collapse and/or unconsciousness. The occurrence of nonspecific nervous disturbances as an

after-effect of acute exposures is dependent on duration of unconsciousness and/or severity of circulatory failure. Breathlessness, nervous irritability, and unsteadiness in walking have been observed to persist for a period of several weeks. Inhalation of still lower concentrations (250-500 ppm) yields signs and symptoms of mild poisoning, characterized by vertigo, drowsiness, headache, and nausea. Rapid recovery from these symptoms usually occurs following cessation of exposure.

These effects due to acute exposures to high concentrations of benzene have been recognized for many years and are well documented in classic toxicological textbooks and literature.

Direct contact with the liquid may cause erythema and blistering. Prolonged or repeated skin contact, even with small quantities of benzene, has been associated with the development of dry, scaly dermatitis, or with secondary dermal infections.

C. CHRONIC EFFECTS

1. *Background.* The primary focus of this regulation is to minimize worker risk resulting from chronic exposure to low levels of benzene. These effects of benzene exposure in man have been recognized for approximately 80 years. As benzene attacks the hematopoietic (blood-forming) systems and especially the bone marrow, its toxicity is manifested primarily by alterations in the level of the formed elements in the circulating blood (red cells, white cells, and platelets). The degree of severity ranges from mild and transient episodes to severe and fatal disorders. The mechanism by which benzene produces its toxic effects, although under investigation, is still unknown. (Goldstein, Ex. 43.B, p. 132).

The adverse hematopoietic effects of benzene, including leukemia, have been documented in a variety of industries and occupations and include the rubber, shoe, rotogravure, painting, chemical processing, can manufacturing indus-

tries and more recently, the manufacture of natural rubber cast film. These studies range from single case reports, through cross-sectional studies to retrospective studies of morbidity-mortality among a defined cohort of workers industrially exposed to benzene. An important distinction among these investigations is that the cross-sectional method detects cases of mild benzene-induced hematotoxic effects in current employees who do not demonstrate signs of overt toxicity, whereas the retrospective method detects overt and fatal toxic effects subsequent to termination of employment.

OSHA is aware of the varying quality of the individually reported studies. Based on a review of the entire set of studies, taken as a whole, the accumulated evidence is conclusive that benzene exposure is causally related to the induction of leukemia (a cancer of the blood-forming system), various cytopenias (decreased levels of a formed element in the circulating blood), aplastic anemia (a nonfunctioning bone marrow) and to development of chromosomal aberrations.

The evidence supportive of this conclusion is derived from: (a) A high degree of association of blood dyscrasias with benzene exposure; (b) the apparent lack of a similar association with other known volatile chemicals in the same workplace; (c) outbreaks of hematotoxicity temporarily related to the introduction of benzene to an industry and conversely, a reduction in blood-related disease when other solvents are substituted for benzene; and (d) the experimental demonstration of marrow toxicity in animals solely exposed to benzene (Goldstein, Ex. 43B, p. 133).

The following studies are representative, although by no means all inclusive, of the published literature on the chronic effects of benzene exposure. These investigations do, however, illustrate the diversity and variability of the effects which dominate published reports. There are also several recent reviews and summaries concerning the hema-

tological effects resulting from benzene exposure (See: Vigliani and Forni, Ex. 2-15; National Research Council, Ex. 2-4; NIOSH, Ex. 2-3, 2-5; NYU report; Ex. 43.B and ORC/Jandl, P.C. 34; Snyder and Kocsis, Ex. 2.B-288, and the International Workshop on the Toxicology of Benzene ("International Workshop") (Ex. 18).

2. *Non-Malignant Blood Disorders.*

a. *Human studies.* The most common effect resulting from chronic exposure to benzene is a decrease in the levels of erythrocytes (red blood cells), leukocytes (white blood cells) and thrombocytes (platelets) in the circulating blood. In simplified terms, a decline in red cells is termed anemia, a decrease in the level of white cells is leukopenia and a decline in the platelet count is called thrombocytopenia. Persons found to have depressed blood cell counts may or may not depending, in part on the severity of the decline, display overt physical symptoms. Anemia results in a decreased capacity of the blood to transport oxygen to various parts of the body, and persons so diagnosed may appear pale and weak and fatigue easily. However, the non-specific symptoms may develop gradually and not require medical attention until there are significant declines in red cell counts and blood hemoglobins. Chronic anemia may also result in physical adjustments by the cardiovascular system and exacerbate difficulties in those with coexisting disease such as coronary insufficiency or chronic obstructive bronchopulmonary disease (Wintrobe, Ex. 2A-107, p. 532). Since white cells provide a defense against many diseases, persons with leukopenia are prone to recurrent infections. Goldstein has written that "Infections are a dreaded complication of bone marrow toxicity and not uncommonly associated with a cause of death in benzene-induced pancytopenia"[2] (Ex. 43B, p. 144). Thrombocytopenia results in an

[2] In the NYU review of "A Critical Evaluation of Benzene Toxicity", Goldstein uses the term pancytopenia in a general sense,

impaired clotting of the blood, and persons with this disorder may exhibit bleeding tendencies, such as easy bruising, nosebleeds, and hemorrhage.

Pancytopenia and aplastic anemia are more serious conditions in which all 3 formed elements are depressed. These non-cancerous diseases may, in and of themselves, be fatal. An additional concern is that some or all of these disorders induced by benzene, may, if allowed to continue, either progress to or represent a preleukemia stage which may eventually evolve into a frank leukemia.

Among the early studies describing benzene toxicity was that of Selling (Ex. 2-12). He observed a significant depression in the levels of circulating blood cells in workers employed where benzene was used as a solvent for rubber. Because of the depressed condition seen in the marrow of

defined as a decrease in the level of circulatory erythrocytes, granulocytes, and platelets. His rationale is that there is excellent evidence which suggests that all of these cell lines originate from a common precursor stem cell (Exhibit 43B, p. 135). While noting that aplastic anemia is, in a pure sense, an absence or a decrease in identifiable granulocyte, erythrocyte, and platelet precursors within the marrow itself, Goldstein finds that it is useful to include aplastic anemia or hypoplastic anemia under the category of pancytopenia. This is because in some human cases of pancytopenia induced by benzene and in some animal experiments, a hyperplasia of the bone marrow is observed; also there exists the possibility that sampling errors may affect attempts to quantitate bone marrow precursor cells, since only a small fraction of the marrow is observed by aspiration techniques.

However, Jandl feels that aplastic anemia is not a sufficiently explicit term to describe failure of "marrow to provide an adequate population of dividing blood cells for the 3 series of formed elements," and observes that the terminology "aplastic anemia" has been applied to states of chronic or non-acute marrow suppression, whether or not anemia was the most striking feature (ORC/Jandl PC 34, p. 83, Add. 3(i)). Other terms used synonymously have been "hypoplastic anemia, bone marrow failure, refractory

his patients and the results of extensive animal experiments (where he was able to produce both destructive and "regenerative" effects by subcutaneous injection of benzene), Selling suggested that the cause of the cytopenias observed in the workers was due to an aplasia of the marrow.

An important early milestone of the benzene literature was the 1922 report by Hamilton entitled "The Growing Menace of Benzene (Benzol) Poisioning in American Industry" (Ex. 159.C).

The document attempted to alert the medical community to the dangers associated with chronic benzene poisoning which was less well known than acute toxicity. This was followed several years later by the reports of the National Safety Council (NSC) which reported the prevalence of known cases by chronic benzene poisoning. These results are summarized by Jandl as follows:

> The magnitude of toxicity—primarily consisting of lowered blood cell counts—was shockingly high. Over half of the workers exposed for a year or more had abnormalities or cytopenias of the blood cells, a great

anemia and aregenerative anemia." Based on the degree of severity exhibited, Jandl recognizes 2 phases of marrow failure:

"[B]y convention, a diminution in the level of all blood cells produced in the marrow accompanied by evidence that bone marrow cellularity is deficient, but from which recovery occurs, usually, termed 'pancytopenia.' And by convention, a more sustained, more severe, more likely fatal suppression of the marrow is termed 'aplastic anemia.'" (P.C. 26B, p. 83, Add. 3(i)).

OSHA recognizes the usefulness and the technical reasons for Jandl's establishment of quantitative diagnostic criteria for various non-malignant blood disorders and his "reassignment" of diagnoses contained in the literature according to this classification scheme. However, for convenience sake, the terms "pancytopenia" and "aplastic anemia" are used interchangeably throughout the preamble except when discussing particular points contained in Jandl's review. In these instances, the terminology will reflect Jandl's more definitive nomenclature.

> proportion had pancytopenia, and a number of deaths were noted, characterized by preceding pallor, weakness, easy brusing, hemorrhage and often fulminant infections (ORC/Jandl, PC 34, p. 10-11).

More data relating occupational exposure to benzene to the occurrence of blood disorders was provided in the late 30's and mid-40's by the studies of Greenburg et al., Mallory et al., and those of Hardy and Elkins.

Greenburg and co-workers (Ex. 2-8) investigated the problem of benzene toxicity among 332 workers employed in three rotogravure processes in New York City. In addition to physical examinations, including medical and occupational histories and laboratory tests, workplace air samples, and chemical analysis of ink solvents was performed in an attempt to provide a correlation with medical findings. Exposure data in Plant A revealed that of 11 samples taken, 8 were in excess of 100 ppm, in Plant B, 14 of 24 samples showed levels above 100 ppm and in Plant C, 6 of 13 samples exceeded 100 ppm, but of the total 48 samples taken, 33 were below 200 ppm. The medical results revealed that clinically evident degrees of "poisoning" were seen in 130 workers of which 22 had severe poisoning and 6 required hospitalization. Five of the workers with the most severe hematologic pictures expressed no objective complaints, and physical examinations were negative. It is noteworthy that the individual sensitivity to benzene varied greatly. Moreover, the authors noted that the benzene-related blood changes may be persistent and could continue to develop even after exposure had ceased.

In the same year, Mallory et al. (Ex. 2-9) reported autopsy findings in 19 workers exposed to benzene from 6 months to 12 years, but no data from the work environment was available. The author noted that significant changes were consistently found throughout the entire hematopoietic system including the marrow, liver, spleen, and lymph nodes. Of the 19 cases studied, 6 exhibited hypoplasia of the

bone marrow, whereas 9 cases showed hyperplasia and 2 were diagnosed as leukemic (1 acute myeloid; 1 acute leukemic). The authors concluded that exposure to benzene under varying conditions provided diverse reactions and that individual variation was of great importance.

In 1948, Hardy and Elkins (Ex. 2-10) investigated an artificial leather plant in Massachusetts where in 1946, a man employed as a coater for 12 years became ill and died from benzene poisoning. Sixteen of the 52 workers at the plant exhibited a "remarkable deviation" in more than one blood component, but none were clinically ill. Benzene concentrations taken in 1938 ranged from 45 to 80 ppm, and thereafter repeated tests at the work station of the deceased subject revealed a concentration of about 60 ppm. Elkins stated "[D]uring World War II, however, the plant worked long hours, so that presumably his (the decedent's) exposure overall had been greater than would be indicated by the concentration of benzene found" (Elkins, Ex. 156.3, p. 7). However, on the basis of this case, Elkins and others revised the PEL in Massachusetts to 35 ppm. The authors also concluded that workers exposed to benzene should have routine complete blood examinations and stressed the importance of preemployment medical evaluations which should include a medical history and a hematologic baseline.

In 1956, Savilahti reported on 147 workers who used a rubber adhesive dissolved in benzene, and who were exposed to approximately 400 ppm benzene (Ex. 2-95). Blood tests demonstrated hematological deficiencies in 73% of those examined. Thrombocytopenia, the most common symptom, was observed in 62% of those tested, followed by anemia (35%) and leukopenia (32%). Deficiencies in all 3 cell types were observed in 21% of those examined and deficiencies in two cell—types in 14%. As a result of this investigation, the use of benzene as an adhesive solvent was discontinued.

In a nine-year follow-up to the Savilahti report, Hernberg et al. (Ex. 2A-252) reexamined 125 of these workers

previously exposed to benzene who were free of such exposure since 1956. This is one of the few studies available which presents a longitudinal assessment of workers previously exposed to benzene for which follow-up exceeded 2 years. The results showed a greater tendency toward recovery of leukocytes than erythrocytes or platelets; a finding which is in agreement with other investigations. Among male workers, the mean erythrocyte levels remained depressed for 9 years and were significantly less than the values reported for the control group. Despite recovery in the mean level of the platelet counts during the nine-year interval, concentrations for both men and women remained significantly below that of a control group. Based on their findings, the authors stated that "The analysis also showed that the prognosis of the severe cases did not differ from that of the mild ones, provided the acute stage had been passed." (p. 204).

Worker exposure in the rubber coating industry to petroleum naphtha containing up to about 10% benzene was reported by Pagnotto et al. in 1961 (Ex. 159A). Several hemoglobin values less than the lower limit of normal were observed among 47 men given blood examinations. Benzene concentrations ranged from essentially zero to over 100 ppm, with a substantial number between 10 and 25 ppm. Their exposure to benzene ceased in 1965.

In 1973, blood tests were repeated on 18 of these workers who were still employed by the firm, the others having retired or left for other jobs (Pagnotto et al., Ex. 156.3.B). Selection bias may be inherent in this report as the retirees who were excluded may have been more likely to have had blood abnormalities. The blood picture of 14 out of 18 employees was characterized as "essentially normal" (Elkins, Ex. 156.3, p. 9); of the remaining 4, one was anemic, 2 were leukopenic and 1 was both anemic and exhibited leukocytosis (an elevated white blood cell count).

In 1969 Klinche et al, reported hematological damage at

relatively low benzene concentrations (Ex. 2B-304). Eighteen roofers engaged in painting operations for an average of 17 years were investigated. Based upon a careful evaluation of the available results of hematological examinations, 6 were classified as suffering from early stages of benzene intoxication, 7 were suspected of chronic benzene intoxication and the remaining 5 were classified as having a normal blood picture. The paint solvent contained 0.12 percent benzene and benzene concentrations (as determined by Drager gas detector tubes) ranged from trace amounts to 15 ppm. Concentrations of toluene and xylene vapor up to 133 ppm were also found. It was not possible to quantitate past exposure to aromatic solvents. The authors concluded however, that:

> In the case of painted or coated areas of sufficient size, even small traces of these aromatics in the work material (benzene, toluene, and xylene) even in the open air, can cause respiratory air concentrations of the level of the MAC value (15 ppm for benzene). After the workers have been exposed for a sufficiently long time, one must assume that hematological damage will result.

In a recent survey, Aksoy et al. compared the hematological findings of 217 apparently healthy male workers who were exposed to as much as 210 ppm benzene when adhesives containing benzene were utilized (Ex. 2-11). The duration of exposure ranged from 3 months to 17 years. Hematological abnormalities were seen in 23.5% of the workers. Leukopenia, with or without thrombocytopenia, was the most common finding. In addition, relative to controls, benzene exposed workers were found to have a statistically significant reduction (p less than 0.001) in mean white cell and platelet counts. Aksoy and his colleagues reported a considerable variability in the 11 bone marrow specimens studied. The aspirates showed both hypocellularity and hypercellularity (a decrease and an increase in the number of cells present), a finding consistent with his previous

reports. (See Aksoy et al. Ex. 2A-290). In 33 percent of the workers examined, the hemoglobin levels fell below the lower limit of normal. Aksoy was reluctant to ascribe the anemia to benzene exposure since it was correctable by iron therapy. However, Goldstein commenting on Aksoy's findings that "the mean corpuscular volume (MCV) was in the high normal to slightly elevated range (80-96 um^3) which is unusual for iron deficiency and more in keeping with a benzene effect" (Ex. 43B, p. 140).

In 1977, Dow reported that 2 of the 594 individuals occupationally exposed to benzene died of non-malignant blood disorders, compared to 0.2 deaths expected (DOW/OH/Ex. 154, Table 6). One worker died of pernicious anemia 4 years after retirement. His exposure was estimated to have averaged 30 ppm for approximately 184 months. The second employee, who died of aplastic anemia, had an estimated exposure of 5 ppm for approximately 98 months. Because of the small numbers involved, the significance of Dow's findings is subject to some question, but the trend of excess death is consistent with the evidence presented above.

An issue deserving discussion is the similarity and difference between benzene-induced non-malignant blood disorders and those resulting from other causes. In the NYU report, Goldstein noted that:

> While the literature is inadequate to draw firm conclusions, the progression and outcome [fatality rate] of benzene-induced pancytopenias does not appear to differ substantially from that of published series of patients with idiopathic aplastic anemia (Ex. 43.B, p. 145).[3] (Ex. 43.B, p. 148)

[3] However, Goldstein does suggest three possible differences between benzene-induced pancytopenia and so-called idiopathic aplastic anemia: the first is the observance of marrow hyperplasia in benzene-induced disease; the second is the presence of lymphocytopenia; and the third is "relatively frequent but inconsistent" reports of red blood cell macrocytosis resulting from benzene exposure. (Ex. 43.B, p. 148)

The NRC report comes to a similar conclusion:

> [T]he available evidence does not indicate that the reported benzene-induced blood dyscrasias differ in any way from similar dyscrasias which are caused by other myelotoxic agents or for which the etiology is unknown (NRC, Ex. 2-4, p. 4).

On the other hand, Jandl contends that the high degree of reversibility of benzene-induced non-malignant blood disorders distinguishes these disorders from those caused by other agents which are idiopathic in nature. He reports that the chance for recovery in idiopathic aplastic anemia is 16%, that for drug-related aplastic anemia it is 33% and that based upon a review of 169 patients with benzene-induced aplasia reported between the years 1939-1975, the prognosis for recovery is 87%. (ORC/Jandl, Ex. 34, p. 37). Furthermore, he notes that milder forms of blood disorders resulting from benzene exposure appears to be 100% reversible (ORC/Jandl, PC 34, p. 39).

OSHA is aware that literature indicates that many cases of nonmalignant blood disorders may be reversed. For example, Maugeri has stated:

> the hemopathy due to benzol can, as in most cases studied by us, be cured if it is diagnosed immediately (Maugeri & Pollini Ex. 156. I p. 2).

Hernberg et al. in a follow-up study of 125 workers stated that: "the prognosis of these patients proved to be more favorable than might have been expected." (Ex. 2A-252, p. 209). Also, both Tabershaw and Aksoy have noted the reversibility of various cytopenias (Tr. 2547).

However, certain other investigators report that these disorders have persisted for as long as 12 years after cessation of benzene exposure. Goldwater and Tewksbury noted continued blood abnormalities in 10% of 108 men examined 24 months after exposure ended. (Ex. 141). Helmer observed abnormalities in 25% of 60 patients followed for 16

months, including 2 deaths. Rejcke and Rejskova found that 8 of 4500 workers manifested persistent leukopenia 12 years after exposure. (Cf. Hernberg, Ex. 2A-252, p. 204). Aksoy observed a further distinguishing feature of severe blood disorders resulting from benzene exposure. In over 100 cases of aplastic anemia classified as idiopathic or associated with etiological agents other than benzene, no cases of leukemia were observed (Aksoy, Ex. 60, p. 6A). This contrasts to the development of leukemia among some cases of aplastic anemia associated with benzene exposure.

As is apparent from the above discussion, there is no unanimity of opinion whether benzene-induced blood disorders persists, and are reversible after cessation of benzene exposure and whether such disorders differ from those resulting from other known or unknown causes.

OSHA recognizes that in many cases these disorders appear to be reversible, within the definitions of "normality" or "reversibility" used by the individual authors. However, it is not known whether for particular workers the blood indices actually return to pre-exposed or baseline valves. Because the original literature does not provide suitable long-term longitudinal analysis including adequate sample size, preexposure values nor baseline hematological values for comparative purposes on an individual basis, it is difficult to decide how much reliance can be placed on such studies. Moreover, the evidence is insufficient to determine whether or not individuals who have "recovered" are at greater risk to subsequent development of leukemia.

Finally, OSHA is unable to verify Jandl's quantitative estimates of recovery as the sources selected for his calculations are not adequately presented to permit the development of valid inferences. Consequently, the Agency does not believe it appropriate to conclude that these non-malignant blood disorders will in all cases, be reversed to the individual's normal values.

b. *Animal Studies.* One of the first studies describing experimentally induced benzene toxicity was published by Selling in 1916 (Ex. 2-12). He was able to produce both destructive and "regenerative" effects in rabbits by subcutaneous injections of commercially pure benzene in olive oil. Bone marrow specimens clearly demonstrated a constant, well defined aplasia associated with the disappearance of leukocytes in the peripheral blood. Later studies conducted by Gerarde demonstrated that a reversible hematopoietic injury in rats was produced at a concentration of 1 ml/kg administered by subcutaneous injection for 14 days (Ex. 2-64).

In an extensive review of experimental benzene intoxication (Ex. 43.B, Ch. V), Leong observed that the results from most of the inhalation studies reported up to Spring (1977) are difficult to interpret due to inadequacies in the experimental design. Many of the studies were conducted without proper control groups to allow comparison of hematologic values against experimental results. Factors such as age, sex, strain, hormone status and to a greater extent, emotional reactions of the animals and techniques used for blood sampling are known to affect hematological parameters. Because of these defects, many of the animal studies do not provide sufficiently definitive exposure-effect information.

In 1944, Svirbely and colleagues exposed rats to benzene vapors at a concentration of 1,000 ppm for 7 hours per day, 5 consecutive days a week for 28 weeks (Ex. 2A-201). Benzene-induced leukopenia was observed during the first half of the exposure period, followed by an increase in the white cell count during the latter part of the experiment. The significance of these results is unclear since similar shifts in the white cell count occurred in the non-exposed control group.

The hematological findings obtained in inhalation experiments at lower concentrations have demonstrated consid-

erable variation. Guinea pigs and rats exposed to an average of 88 ppm benzene for 8 hours per day for 5 days a week demonstrated a mild leukopenia after 32 and 136 days of exposure, respectively (Cf. Leong, Ex. 43.B, pp. 89-90). Deichman et al, reported in 1963, that benzene can effect hematological changes, at even lower concentrations (Ex. 2-16). Eight groups of rats were exposed to benzene vapors at average concentrations of 831, 65, 61, 47, 44, 31, 29, and 15 ppm, respectively. The duration of exposure was 5 hours per day, 4 days per week for periods ranging from 5 weeks to 7 months. Exposure to the 3 highest concentrations resulted in significant leukopenia after 2-4 weeks. A moderate, but definite leukopenia was reported in the groups exposed to 47 and 44 ppm after 5 to 8 weeks. No demonstrable alterations were observed at the 3 lowest concentrations during the 7 month experiment.

In a preliminary report submitted to OSHA prior to the rulemaking proceedings, Reinhart found no significant deviation of blood counts in test rats exposed to 388 ppm for 6 hours/day, 5 days a week for 12 consecutive weeks (Ex. 115. B.8). However, significantly depressed WBC counts were observed in mice, while in guinea pigs a progressive leukocytosis was observed which continued even into the post-exposure period. Reinhart used no control group, and the number of animals used per test group is considered to be inadequate.

Finally, Laskin and Goldstein prepared an abstract for the International Workshop on Toxicology of Benzene in Paris, November 9-11, 1976 describing their chronic benzene exposure studies (cf. Snyder, 156.2, p. 5; Ex. 178). For more than two years 150 Sprague-Dawley rats and 300 mice of 3 different strains were exposed to 100 or 300 ppm benzene 6 hours daily, 5 days per week. Anemia was observed in mice but not in rats. However, lymphocytopenia was observed in all animals without similar reduction in the granulocytes until the terminal stages of benzene pois-

oning. This study suggests that lymphocytopenia may be an early marker for benzene toxicity.

Based on the record, the extent of non-malignant blood disorders resulting from benzene exposure is uncertain. Based only on reports contained in the literature, Jandl has calculated a number of cases and deaths annually due to aplastic anemia in the United States. Based upon data derived from several consecutive case series over the past 15 years, Jandl estimates that a 2% "probable" and 2% "possible" benzene etiology for cases of aplastic anemia (presumably not including milder disorders such as pancytopenia). Using the annual figure of 420 cases of aplastic anemia in the United States, Jandl arrived at an approximation that "about 10 and possibly 20 patients die annually due to benzene exposure." (P.C. 26B, p. 40-1, 86-87).

Goldstein suggested several reasons why the true incidence of pancytopenia resulting from benzene exposure may be seriously underestimated (Ex. 43B, pp. 138-39):

(a) That mild cases of pancytopenia may not be discovered unless searched for since they often cause no overt symptoms.

(b) That since hematoxicity induced by benzene is a phenomenon well known to the medical community, such cases tend not to be recorded in the literature, and

(c) In cases of idiopathic aplastic anemia, possible relevant exposure to benzene may have been overlooked.

OSHA believes that the present data does not permit an accurate assessment of the morbidity or mortality for benzene-induced on nonmalignant blood disorders.

C. CONCLUSIONS

Industry participants have argued that the present permissible exposure limits (10 ppm TWA and 25 ppm ceiling) provide adequate protection against the non-malignant effects of chronic exposure to benzene. (AISI brief, PC 36, p. 51, 66; MCA brief, PC 35, p. 32).

Snyder has noted, "[i]n both animals and man the lowest level of exposure demonstrated to produce bone marrow toxicity was approximately 40 ppm." (Tr. 3224-25). Elkins believes that threshold-for injury to the blood-forming system is between 25 to 50 ppm (Tr. 3210); Tabershaw (Ex. 149A, p. 6) stated that cytopenia has not been demonstrated to occur below 25 ppm. ACGIH (Ex. 156.3D) and the International Workshop on Toxicology for Benzene, both recommended a 10 ppm TWA and 25 ppm ceiling (Ex. 17).

Attention was drawn to the Dow morbidity study in which no abnormal blood findings were observed among 287 workers exposed to benzene for 1 to 20 years, at concentrations estimated to range from 2 to 30 ppm (Ex. 154).

The Pennzoil Company commented to OSHA that from the past nine years, 160 employees exposed to 1-5 ppm benzene have been monitored by blood test, with up to 25 years work experience for some there has been "no clinical evidence of medical problems associated with benzene." (Ex. 41.1, p. 2). However, no data were presented to allow an assessment of this statement. Others have reported similar views to OSHA again without formal presentation of data. (Joyner, Tr. 2286-87; Texaco, Ex. 41-4, p. 2, P.P.G. Industries, Ex. 6-41, p. 2 and Up John, Ex. 6-4, p. 1). It should be noted that these submissions were characterized by the American Iron and Steel Institute as largely "* * * anecdotal in nature" (Ex. 36, p. 64). In further support of its position, industry cites the 1974 NIOSH criteria document recommendation that a 10 ppm TWA as a "conservative limit" (Ex. 2-2, p. 73).

It is clear, there is no dispute that bone marrow toxicity can result from exposure to benzene above 25-40 ppm range. Furthermore, it is recognized that higher dosages produce increased response and that lower dosages are associated

with reduced response. It is not clear, what adverse health effects occur below 20 ppm.

There are suggestions of hematological alterations (other than chromosomal aberrations) at concentrations below 25 ppm. Pagnotto et al. indicated that such effects occurred among workers employed in rubber coating industry exposed to concentrations for the most part between 6 and 25 ppm benzene (Ex 2A-116; Tr. pp. 360-361). Horiguchi has reported small changes in leukocyte function concentrations as low as 10 ppm, in the absence of any marrow change and with only slight variations in leukocyte count and leukocyt phagocytic activity among workers exposed to benzene in concentrations of 0.8-6 ppm (Ex 2A-161, p. 7). And there are also other reports of less apparent effects at airborne levels of 6-16 ppm in workers who do not exhibit characteristic hematological abnormalities. (Kahn and Muzyka, Ex 2A-260). It is not possible at this time to establish with any confidence a consistent dose-response relationship between benzene exposure and adverse health effects.

Where exposure information is available, it is generally area sampling and not personal exposure data that is reported. It is difficult to determine individual worker exposure based on area sampling. Compounding this difficulty are problems related to the fluctuating character of occupational exposure; the small amount of long-term data; and the fact that in small populations, workers with heightened sensitivity may not be encountered. At lower exposure levels, there is a paucity of data to provide a basis for definitive conclusions as to the extent of nonmalignant effects. In this regard Battle states that:

> [E]ven a cursory study of the literature reveals a distressing lack of exposure-hematologic effect data particularly in the low benzene exposure area of less than 10 parts per million. (PC 26C, p. 2).

Moreover, the absence of pre-exposure hematological values for comparative purposes limits the usefulness of the

few studies and reports which are available, because we cannot tell whether a particular worker studied with blood values at either extreme of the normal range is suffering adverse effects. Therefore, the available literature is insufficient to permit construction of dose-effect curve.

As indicated above, the quality of evidence available in the record is considered insufficient to permit meaningful conclusions concerning exposure to benzene at low levels and resulting health effects. Industry participants have cited the 10 ppm level established by the ACGIH as evidence that this level can be considered safe. However, in establishing TLV's, ACGIH recognizes that for some workers harmful health effects may result from exposure to the toxic substance at levels below the TLV. Therefore, the 10 ppm TLV for benzene is recognized by ACGIH as a level which does not protect all workers from material impairment of health.

Leukemia aside, with benzene we are dealing with an etiological agent well-documented to produce a variety of blood abnormalities, some of which are fatal. OSHA is aware of several studies reporting blood abnormalities at levels below 25 ppm, at levels perhaps as low as 10 ppm. Because of these considerations, and the wide range of human sensitivity to benzene, OSHA cannot determine a minimum effect level for benzene and, furthermore, cannot conclude that 10 ppm provides sufficient protection against non-neoplastic effects to all workers. OSHA recognizes that prudent public health policy, and established toxicological principles necessitates setting the permissible exposure limit sufficiently below the levels at which adverse effects have been observed to assure adequate protection for all exposed employees. It is customary to use a safety factor of 10-100 or greater depending on the seriousness of the toxic effects and the nature of the data being relied upon. That is, the lowest levels at which effects had been observed would be reduced by the safety factor chosen in establishing

the exposure limit. Taking this approach in the case of benzene would lead to a permissible exposure substantially less than 10 ppm without regard to the issue of leukemia and the view that no safe level can be established for the carcinogenic risk.

IV. Leukemia

A. Definition and Description of the Disease

Robbins defines leukemia as:

> Leukemia may best be considered as a neoplasm (cancer) of the white blood cells and is so classified in the International Lists of Causes of Death. It is characterized chiefly by: The appearance of abnormal, immature white cells in the circulating blood; diffuse and almost total replacement of the bone marrow with the leukemic cells; and widespread infiltrates of the liver, spleen, and other tissues, analogous to metastatic dissemination of solid tissue cancer. (Ex. 2-24, p. 728).

Once leukemia is diagnosed there is virtually no chance of recovery. There are different categories of leukemia, depending on the duration of the disease, i.e., acute or chronic; an increase or non-increase in the number of abnormal cells, i.e., leukemia or aleukemia; and the cell type involved, i.e., myelord, monocytic or lymphoid. Goldstein also emphasizes that, "there are other differences between various subtypes of leukemia in terms of incidence, clinical course, prognosis and presumably etiological mechanism" (Ex 43B, p. 156).

The most prevalent subtype of leukemia in adults, and the type most commonly associated with benzene is acute myelogenous leukemia (AML). This disease is variously known as acute myeloid leukemia, acute granulocytic leukemia, and acute myeloblastic leukemia (ORC/Jandl, PC 34). There are several variants of AML, probably related to the pluripotential of the precursor cell and include erythroleukemia, (DiGuglielmo's Syndrome) and acute

monocytic leukemia (myelomonocytic, or monomyelocytic). (ORC/Jandl, PC 34, p. 71).

Despite advances in leukemia therapy and the fact that half the adults diagnosed with AML enter into a remission (generally averaging 6 to 8 months) the prognosis of this disease remains poor (ORC/Jandl, P.C. 34, p. 73). Those who enter into remission have life expectancies averaging from 12 to 18 months, and those who fail to respond to therapy have a 50 percent survival rate of only 3 to 6 months. Aksoy noted that in his experience, for cases of benzene-induced leukemias, the period of survival after discovery was short, usually less than 6 months (Tr-275).

Myeloproliferative disorders, including chronic myelogenous leukemia (CML) have only occasionally been attributed to benzene. Lymphocytic leukemia is also subdivided into acute and chronic subtypes. The acute form (ALL), the type commonly seen in children, has only rarely been associated with benzene exposure. Chronic lymphocytic leukemia (CLL), a slowly progressive disease, and often not a cause of death, generally occurs late in life. There have been several reports associating CLL with benzene, most particularly in several reports of French origin. The evidence as to chronic lymphocytic leukemia, which will be discussed in detail later, does not appear to be conclusive.

B. Studies—Human

Evidence in the record clearly demonstrates that benzene is a human leukemogen. Aksoy testified that the first case of leukemia due to benzene exposure was that published by Noir and Claude in France in 1897. (Aksoy, Tr. 154). In 1939, Mallory, et al. described two cases of leukemia resulting from chronic exposure to benzene which supplemented ten previously reported in 1935 by Penati and Vigliani. (Mallory, Ex. 2-9), Mallory et al. stated:

> Certainly no more favorable conditions for the de-

velopment of neoplasm can be imagined than prolonged and intense stimulation of reproductive activity, and simultaneous arrest of maturation.

The evidence that chronic exposure to benzene produces leukemia in human beings is still incomplete but it is accumulating at a rate and to a volume which command serious consideration. (Ex. 2-9, p. 365).

In 1965, in a partial review of the literature, Browning tabulated 61 cases of leukemia among individuals having reported prior exposure to benzene (Ex 2-31). The majority (40) were of the myeloid series—including 12 cases of erythroleukemia, 7 were classified as lymphatic and the remaining 14 grouped under the heading of "aleukemic leukemia" (a type characterized by a decline in white blood cell number).

Vigliani and Saita, in their review of 47 individuals suffering from benzene hematoxicity between the period of 1942 and 1963, presented clinical and laboratory accounts of six additional cases, all of whom were diagnosed as having haemocytoblastic leukemia (Ex 2-27). The duration of exposure of these individuals to resins, inks, varnishes, or glues containing varying concentrations of benzene ranged up to 19 years. Data on the concentrations of benzene in the workplace environment were extremely limited or nonexistent. Occupational histories and medical status prior to the final diagnoses were not available, but the authors stated that "attribution of the cases (of leukemia cited) to the exposure cannot be doubted." During the years 1962-63, Vigliani and Saita noted a sharp rise in the diagnosis of leukemia among individuals having reported prior exposure to benzene which coincided with an increase in the number of newly diagnosed benzene poisoning cases. The risk of acute leukemia for the workers exposed to benzene in Milan and Pavia was estimated to be about 20 times greater than the risk for the general adult population. (Ex. 2-27). In 1975, Vigliani and Forni observed that in the rotogravure industry no new cases of aplastic anemia nor of leukemia

were found among workers exposed solely to toluene after this solvent was substituted for benzene in 1964. Although there have been some reports of hematological disorders associated with toluene exposure (See Girard et al., Ex. 2B-283), the finding of Vigliani is in concert with the conclusion of Brair that, toluene and benzene are "* * * quite different chemical entities from toxicological and pharmacological points of view" and that, "toluene free from benzene can be safely used in industry as a suitable solvent in replacement of benzene." (Ex. 39-5, p. 7). Vigliani and coworkers also observed that workers exposed to toluene did not exhibit chromosomal aberrations, a "finding" observed by these authors in employees who worked with benzene.

In 1972, Aksoy et al. reported the deaths of 4 Turkish shoemakers resulting from their exposure to benzene for periods ranging from 6 to 14 years (Ex 2-29). At the time of the study, air concentrations were found to be between 150-210 ppm of benzene. Previous occupational exposure data were not provided. Two of the four patients developed acute leukemia approximately two and three years after the occurrence of aplastic anemia, although the other two did not. These case reports are supplemented by surveys of newly diagnosed cases in a medical referral area. Aksoy summarized and updated his findings at the benzene rulemaking (Ex 60). He pointed out that from 1967 to 1973, he had observed 26 patients with acute leukemia or preleukemia [4] associated with benzene exposure. Based on a population of 28,500 shoeworkers in the area, Aksoy estimated the incidence of leukemia to be twice the prevailing value of 6/100,000 observed in the general population of Western nations. From September 1973 to 1975, 14 additional cases were admitted to the hematology departments in Istanbul

[4] The criteria used for the diagnosis of preleukemia were similar to those of Wintrobe: "[P]releukemia seems a reasonable term * * * when this diagnosis of AML may be suspected but cannot be made with any confidence." (Ex. 2-107, p. 1477).

and Cerraphasa Medical Schools making a total of 40 in all. Thirty-four of these patients were among the groups of shoeworkers described previously. Aksoy either examined the cases personally or reviewed the charts.

API has criticized Aksoy's use of the baseline figure of 6/100,000, citing a statement from Clemmenson, that the incidence rate for a standard European popuiation is 8 to 14/100,000 (API Ex. pp. 50-51). However, Aksoy has testified that the two-fold excess estimate among benzene/exposed shoeworkers may be underestimated since the incidence of leukemia among the Turkish population is only 3.0 per 100,000. Moreover, Aksoy stated that "undoubtedly there were other additional patients among shoeworkers who were not included in our study" (Ex. 61, p. 2). Aksoy's findings of a decline in leukemia cases during the past several years after other solvents were substituted for benzene (Aksoy, Ex. 61, 99, pp. 2-3) further provides, in an inverse manner, additional supportive evidence for the causal relationship between benzene and leukemia. This finding reinforces the results of Vigliani discussed above.

In his testimony, Marvin Sakol, an Akron hematologist, described what he considered an epidemic of a rare form of leukemia among workers employed in a small department at a local industry (Ex. 61). Over a nine-year period, beginning in 1954, he observed nine cases of acute myeloblastic leukemia, including "at least four and probably all nine" with DiGuglielmo leukemia (erythroleukemia). Due to the rarity of erythroleukemia Vigliani noted that the 20 or more cases attributable to benzene reported in the literature seem to be significant (Ex. 2-49). Diagnoses from slides in some of Sakol's cases were confirmed personally by DiGuglielmo. He learned with much difficulty that all of these cases were exposed to benzene while employed in a Pliofilm operation at a plant subsequently studied by Infante et al. Sakol testified that he had knowledge of additional cases of benzene-related leukemia which have not been included in the

NIOSH study. These cases may never be recorded officially because the families refused permission to release the names of the decedents for fear of loss of compensation and job. This testimony indicates an underestimation of the leukemic risk among Pliofilm workers.

Based on the hypothesis that the risk of leukemia was higher among workers who were exposed to benzene and medical X-rays, Ishimaru et al. conducted a retrospective epidemiological investigation examining the relationship between occupation and environmental factors, other than A-bomb exposure, and the incidence of leukemia in Nagasaki and Hiroshima between 1945 and 1967 (Ex. 2-33). Fifteen occupations were selected in which there had been exposure to either medical X-rays or solvents, especially benzene and its derivatives. This case-control study compared all cases diagnosed as definite or probable leukemias between 1945 and 1967 and residing at the time of the onset of the disease, in Hiroshima or Nagasaki. Controls were matched for city, sex, date of birth ($\pm$ 30 months), distance from the atomic bomb explosion, and residence in either city at the onset of disease. Four hundred ninety-two leukemia cases were identified, and matched controls were obtained for 413. Three hundred and three adult cases with the onset of leukemia at age 15 years or over and their controls were compared. The risk of leukemia was found to be significantly higher (about 2.5 times greater) among those with a history of employment in occupations in which various volatile solvents were used as compared to those without. The relative risk was 1.8 times higher for chronic leukemia and 2.9 times higher for acute. Eighteen of the leukemia cases associated with solvents were located in distant and nonexposed radiation areas and were considered too far from the A-bomb exposion for radiation to have enhanced the increased risk. Accepting the source of error inherent in the method which was used to collect the data, the results of this study nonetheless reinforce the observa-

tion that an increase in leukemia existed in that portion of the population exposed to radiation and employed in an occupation where solvents especially benzene, were used.

In 1970, Girard et al. published an epidemiological study (Ex. 2B-283) undertaken to determine previous exposure to benzene or toluene in 401 patients suffering from malignant hemopathies. Extensive interviews about their work environment and chemical analyses of solvents were utilized to estimate exposure. Their findings demonstrated that compared to a control group admitted for non-hematological diseases there was a statistically significant greater frequency of past exposures to benzene or toluene among subjects with aplastic anemia, chronic lymphocytic leukemia and acute leukemia.

In April 1977, NIOSH submitted to OSHA a preliminary report by Infante et al. of a study of leukemia among benzene-exposed workers employed in the production of natural rubber cast film (Pliofilm) (Ex. 2-57, Ex. 2A-271).

The study included all white males assigned to the Pliofilm production area who were hourly employees and who at any time between January 1, 1940 and December 31, 1949 had direct exposure to benzene at the Goodyear Akron and St. Mary's plants. Only the men employed in a section having known potential exposure to benzene ("wet side" in industry terminology (Rinsky, Tr. 818-820)) were included in the cohort. Men employed in the Pliofilm operations, but not in production jobs (so called "dry side" workers) were not included in the study. Follow-up of vital status was attempted from termination of employment to June 30, 1975 and was achieved for 75% of the total of 748 benzene-exposed workers. So as not to overestimate the true risk of lymphatic and hematopoietic malignancies associated with benzene exposure, the 25% of the cohort for whom vital status was not determined were assumed to be alive. Little or no quantitative exposure data existed for these plants.

Causes of death were determined from death certificates, and person-years at risk were determined by a modified life-table method. Person-years of observation and causes of death were determined from January 1, 1950 to December 31, 1975. Two control populations were used to generate the numbers of expected deaths in the study. The first comprised the U.S. white male population, while the second was white males employed in an Ohio fibrous glass production facility during the 1940's and who had achieved five years of employment by June 1, 1972.

The most striking finding was the observation of a statistically significant (p less than 0.002) five-fold increased risk of dying of leukemia compared to the U.S. male rates (7 deaths observed vs. 1.38 deaths expected, p less than 0.002), as well as to the fibrous glass workers (7 deaths observed, 1.48 deaths expected, p less than 0.002).

Criticisms of various aspects of this study were raised by participants to the rulemaking. The issue of what level of benzene the workers in the Infante et al. cohort were exposed to was the most discussed area. Participants criticized the information available in the Infante study. The study referred to a November 1946 report of the Industrial Commission of Ohio which indicated that: "Tests were made with benzol detectors and the results indicate that concentrations have been reduced to a safe level, and in most instances range from 0 to 10 or 15 parts per million." Comments at the hearing demonstrated that there were area exposures during this study period exceeding these levels, at times reaching values of hundreds of parts per million. Since no personal monitoring data are available, any conclusion regarding the actual individual time-weighted average exposure is speculative. Because of the lack of definitive exposure data, OSHA cannot derive any conclusions linking the excess leukemia risk observed with any specific exposure level.

The study was also criticized for combining the two sepa-

rate plants in the same analysis. It was suggested that an independent analysis of the two plants would produce different results, thereby suggesting that factors other than similar exposure to a single agent (benzene) contribute to the excess leukemia. (Lamm, Tr. 2538). OSHA believes that the use of non-age-adjusted leukemia death rates, as utilized in Lamm's analysis, is inappropriate for the assessment of an event associated with age. Therefore, OSHA believes that this criticism is unsupportable on this basis. Moreover, the cohorts were combined based on the similarity of the processes in the two plants (Tr. 842). Also, because of the small number of subjects in the study cohort, the authors stated that it would be inappropriate to analyze the data separately for the two plants. (Infante, Tr. 935, 796-97).

A question has been raised by industry participants as to the validity of excluding the "dry side" (Photofilm finishing) workers from the study cohort (Lamm, Tr. 2638-29; API, PC 33, p. 42-43). As explained by one of the authors, these workers were never intended for inclusion in the cohort following discussion with company personnel indicating there was no benzene exposure on the dry side (Infante, Tr. 929-30). Testimony was also offered that if "dry side" employees had job operations which kept them predominantly on the wet side of the plant, then those employees were included in the cohort (Tr. 931). Limited data subsequently released by the University of North Carolina at the OSHA hearing indicated that there may have been some benzene exposure (0, 11.8 20 ppm) on the "dry side". However, there were only 3 sample points and no details were given as to sampling locations, duration of sampling, or definition of departments, to permit interpretation of this information (Ex. 187B.6, Table 3, p. 10). Infante testified that a cursory examination of "dry side" workers revealed no leukemias. However, Infante stated, "* * * there really are not enough people who are employed on the dry side who never went into the wet side to make a meaningful conclusion about that (leukemia deaths from exposure among workers on the dry side)" (Tr. 930). Based upon the above considerations, it appears that the "dry side" workers should not have been included as was the case.

A question was raised as to whether the study demonstrated the true risk of leukemia among workers exposed to benzene (Tr. 311). Sakol referenced two cases of leukemia at the same plant which he personally diagnosed, which were not so certified on death certificates. He cited these cases in support of the substantial underascertainment of leukemia mortality in the study of Infante et al., due to their sole reliance on death certificates.

The use of the Connecticut Tumor Registry data to determine the expected number of type-specific leukemia deaths for the Infante cohort was criticized. Jandl calculates that the tenfold excess risk of myelogenous and monocytic leukemia found by Infante et. al. may have been off by at most a factor of two. (ORC/Jandl, PC 34, p. 77). (Also, there is a counter-balancing underestimate of the risk because at the time of the report, only 75 percent followup had been completed and the remaining 20 percent of the study population were all regarded in the statistics as being alive at the end of the study period.) Both the strengths and weaknesses of the Infante et. al. study have been carefully evaluated by this Agency. OSHA believes this study is one of the more definitive investigations in the benzene literature and provides additional evidence supportive of earlier studies which implicate benzene exposure and the subsequent development of leukemia.

An opposite result was obtained in a Tabershaw-Cooper Associates Inc. mortality study of petroleum refinery workers (Ex. 2-5a). The study population was a sample of workers from the 251 U.S. refineries operating in 1971. The authors attempted to select a sample of 17 U.S. refineries to give a representative distribution with respect to geographic area, ownership, and size. Hourly workers with

more than one year of work experience between January 1, 1962, and December 31, 1971, were studied. All workers were classified as to their potential hydrocarbon exposure. The authors reported that better than 94% follow-up was achieved. An excess mortality from lymphoma was observed although it did not achieve statistical significance.

Subsequently, the study was expanded to include 5,145 workers who had been hired on or before 1943 and who were working sometime during January 1, 1962, through December 31, 1971. No excess mortality from leukemia or lymphomas was observed in this subpopulation having 20 or more years since first hydrocarbon exposure. Gaffney, one of the authors of the study, stated that the study had been commissioned not specifically to study the effects of benzene, and in fact he could not delineate what proportion of the study population had ever been exposed to benzene (Tr. 1343-1344). Moreover, as adduced during the hearing, Gaffey acknowledged that there was no industrial hygiene assessment of the work environment (Tr. 1251) to provide the basis for identifying which workers may have been exposed to benzene.

Because this study was designed to assess potential effects of "hydrocarbon" and not benzene exposure and since no group of workers exposed to benzene was clearly identified, this study provides no relevant information as to the leukemogenic risk of exposure to benzene. Therefore, OSHA does not view this study as providing negative proof that benzene does not cause leukemia.

Dow submitted a study which addressed the incidence and mortality of leukemia among benzene-exposed workers (Ex. 154). The mortality experience for all employees occupationally exposed to benzene from 1940 to 1973 was studied. Expected deaths were calculated using age-cause-specific mortality rates for the corresponding U.S. white male population from 1942 to 1972. Each of the 594 workers were classified in approximate benzene exposure categories. A

rough cumulative dosage was calculated. When consideration was given to the incidence of myelocytic leukemia, the authors concluded that a statistically significant excess was demonstrated (3 deaths observed vs. 0.8 expected, p less than 0.05) (Ex. 154, p. 12). Mortality data were analyzed by production areas and according to cumulative dosage and length of occupational exposure. Those people in the cohort who had exposures to known carcinogens were excluded from analyses dealing with dose-response in relation to benzene exposure.

An increase in leukemia incidence was observed in the population where 2 deaths were observed vs. 1.0 expected. An additional death resulting from myelogenous leukemia was identified among the study cohort subsequent to the earlier published report. Based upon their findings the authors stated that:

> In these cases, varied work histories, low levels of potential benzene exposure relative to other employees in the cohort, and the lack of information in regard to total medical history made a retrospective assessment of the possible relationship to benzene exposure very judgmental. (Ott, Ex. 154, p. 12.)

However, based upon the recent finding of the third death due to leukemia, Dow lowered its internal ceiling limit from 25 ppm to 10 ppm (Ex. 82).

In addition to the 3 deaths reported due to leukemia, 2 deaths attributable to non-malignant blood disorders were also reported: aplastic anemia and pernicious anemia. (OH, Ex. 156, p. 9.) Deaths attributed to aplastic anemia without examination of bone marrow aspirates, may in actuality, be due to leukemia (Vigliani Ex. 2-15, p. 123), thereby potentially resulting in an underestimation of leukemia risk among the benzene-exposed cohort.

OSHA recognizes that the decedents were for the most part exposed to relatively low concentrations of benzene, and no leukemia deaths occurred in the higher exposure

groups. However, because of the small population size as well as the possibility of sensitivity of those individuals developing leukemia, it cannot be concluded that these deaths are not caused by benzene exposure.

OSHA does conclude that the findings of this study are consistent with the findings of many studies that there is an excess leukemia risk among benzene exposed employees.

Allied Chemical Corp. submitted a post-hearing comment containing mortality data for employees with potential benzene exposure (P.C. 22). Death certificates were obtained for all workers dying between 1961 and mid-1977. Rough exposure information was derived by back extrapolation, limited exposure data, and subjective reports of employees regarding signs and symptoms. Based on these estimates of benzene exposure, there was no observed cluster of leukemia in operations having benzene exposure. Because this study was presented to OSHA after the hearing closed, more specific details concerning the estimate of exposure, the method utilized for obtaining estimates of person-years at risk, or how the death certificates were coded were not obtained.

In 1974, Thorpe reported that the incidence of leukemia, among a population of 38,000 workers exposed to low levels of benzene over a ten year period (1962-1972), was not statistically different from that expected on the basis of the general population (Ex. 2-34). However, the study has been criticized for the relaxed casefinding techniques and analytical methods (Brown, Ex. 2A-35). Thorpe himself acknowledged the following serious methodologic deficiencies:

1. Validity of leukemic diagnoses.
2. Quantitative determination of exposure levels.
3. Adequacy of retiree follow-up.
4. Complete occupational histories.

As in the case of the Tabershaw/Cooper study, OSHA cannot separate the benzene-exposed workers from those

with little or no exposure. This difficulty, compounded by the 4 deficiencies listed above, also precludes reliance upon the finding of the Thorpe study.

University of Pittsburgh investigators (Lloyd, Redmond, Ex. 113) have published a notable series of epidemiological studies of steelworkers mortality. AISI (P.C. 36, pp. 59-60) cited the above studies as evidence of no leukemia risk among benzene-exposed coke oven workers. Most notably, the industry cited the fact that byproduct plant coke oven workers were not found to have been at excess risk (P.C. 36, p. 60) and recommended that coke ovens be excluded from the benzene standard (P.C. 36, p. 100).

However, as Bickmore stated:

> * * * In all 35, the expected, the incident (sic) of mortality and expectation is so low as to preclude any meaningful statistical calculations by the professionals that made the study. (Tr. 3314)

These coke oven worker studies were designed to assess worker risk of exposure to coke oven emissions (Ex. 113 p. 1) (P.C. 27C p. 1, P.C. 27D p. 1). Given the small numbers of observed and expected rates of leukemia, and in the absence of a study designed to assess coke oven worker exposure to benzene, OSHA believes it inappropriate to rely on these studies as evidence that there is not a leukemia risk of exposure to benzene.

During the hearing, Stallones discussed the unpublished study of 3,600 Shell Oil Company workers with "potential" benzene exposure (Ex. 115C.2). Among this population he testified that he observed no excessive leukemia mortality in the three year period ending in 1976. Stallones could not determine how many workers were exposed to benzene. In fact, clerks and office workers were included in the study group. Again, failure to correctly identify or define a benzene-exposed cohort limits the usefulness of this study.

A series of published and unpublished epidemiologic studies investigating the mortality experience of rubber workers have been entered into the hearing record. (McMichaels et al. Ex. 2-36, -37, 2B-295); Monsan and Nakano (Ex. 2-83); Fox et al. (Ex. 2-61); Andjelkovic (Ex. 2-54); Occupation Health Studies Group, UNC (Ex. 187.B). These studies have, in general shown excess of lymphoma and leukemia among rubber workers. The leukemia was predominantly lymphatic, a cell type not commonly associated with benzene. The proportion of rubber workers actually exposed to benzene in these studies is undetermined. The presence of other chemical exposures raises the question of an alternative causative agent for the excess of lymphatic leukemia and lymphoma observed among rubber workers. In view of these considerations, these studies provide no additional evidence for the leukemogenic potential of benzene.

There has been discussion whether benzene is a *primary carcinogen* (can directly effect a neoplastic alteration without host-mediated activation); a *secondary carcinogen* (chemicals which may increase susceptibility of cells, to a primary carcinogen); a *procarcinogen* (requires biochemical alteration prior to effect); or a *co-carcinogen* (which requires the interaction of another chemical to elicit a neoplastic response). Olson, Tr. 2892; NRC, Ex. 2-4, p. ii; API/NPRA Brief, P.C. 33, p. 86-87; Aksoy, Tr. 177; Furst, Tr. 1744; Stockinger; P.C. 32-H, 53); Weisburger, P.C. 32-I; Tabershaw Tr. 2549, 2545). The evidence is, at present, insufficient to choose among these alternatives. Namely, what is apparent, however, is the effect of benzene exposure —a significantly increased risk of death from leukemia.

Types of leukemia clearly associated with benzene exposure include acute myelogenous leukemia (AML) and its variants. For example, Aksoy testified that among 40 cases of leukemia among benzene-exposed workers in Turkey, AML and its variants were the most frequently observed

form (Ex. 60, p. 7). In the experience of Vigliani and his coworkers, only acute or subacute myelogenous leukemias were observed (Ex. 2-49). The predominant cell type found by Infante (Ex. 2A-271) and others were also myelogenous in character. This well-established association between benzene and AML is in concert with the well-known toxic effects of benzene on bone marrow stem cells (Goldstein, Ex. 43B, p. 162).

In contrast to the definitive relationship between benzene and the induction of AML and its variants, there is considerable scientific debate concerning the association between benzene exposure and the development of chronic forms of leukemia (CLL and ML). Jandl has stated that "* * * lymphoid leukemia is not a feature of benzene toxicity." (ORC/Jandl, P.C. 34, p. 59), and Lamm ruled out chronic leukemia, not as a "possibility", but as a "probability" (Tr. 2558). Aksoy found no cases of CML among the workers he studied. (Ex. 60, p. 6-F), and no cases of CLL were seen by the Italian investigators. A different result has been reported by several French studies which have reported a relatively high incidence of CLL. In some instances, there were more cases of CLL than AML. They also report a higher incidence of CML than would be expected based on Aksoy's and Vigliani's findings. Supporting the high incidence of CLL in the French studies is the report by Tarreef which describes 16 cases of leukemia which resulted from long-term exposure to benzene, 3 diagnosed as CLL (Ex. 2-28).

The evidence is inconclusive as to the relationship between benzene exposure and the development of forms of leukemia other than AML and its variants. Vigliani stated (1976) that, although he did not observe chronic leukemias in his series, "there is no *a priori* reason for not accepting them as benzene-induced leukemias * * *" (Ex. 2-49, p. 148). OSHA believes at this time that it is prudent to recognize the possibility that benzene exposure may be related to chronic forms of leukemia.

One of the major issues of this rule-making is whether a blood disorder is a necessary precursor for the subsequent development of leukemia. For example, in 1974 NIOSH speculated as follows:

> It can be postulated that bone marrow changes and blood dyscrasias would precede leukemia if induced by benzene, so that if these changes were prevented leukemia should not result (Ex. 32B).

Aksoy has testified that benzene leukemias usually develop after a previous pancytopenic period. (Tr. 198) Maugeri, reports that, "the leukemias in our cases were always of the acute, aleukemic slow developing type, and they were always preceded by [an] aplastic condition" (Ex. 39-10, p. 2). Snyder remarked that he was unaware of benzene leukemias without previous demonstration of some kind of bone marrow damage (Tr. 3226) and Goldstein has noted that, "there does not appear to be any proven cases of leukemia in the absence of previous pancytopenia" (Ex. 43B, p. 165). But Goldstein cautions that this interpretation is, "open to speculation, especially in view of the paucity of routine laboratory data preceding the onset of leukemia" (Ex. 43B, p. 165).

As observed by Goldsein, since the mechanism by which benzene induces leukemia has not been elucidated, it is possible that leukemia develops, not in response to the pancytopenic effects of benzene, but rather to the direct carcinogenic effect on the marrow hematopoietic stem cells not necessarily accompanied by any other evidence of marrow effect (Ex. 75, p. 3). In such events, protection against non-neoplastic blood disorders would not rule out subsequent development of leukemia.

Vigliani, in discussing the evidence causally relating leukemia to benzene exposure observed that such leukemia may occur, "* * * directly or following aplastic changes in the bone marrow * * *" (Ex. 2-49, p. 148). In response to a question concerning whether aplastic anemia is a necessary precursor for leukemia, Lamm responded in the negative (Tr. 2562). Also, Browning in 1965 observed that, "benzene leukemia is frequently superimposed upon a condition of aplastic anemia, *but it can develop without a preceding peripheral blood picture characteristic of bone marrow aplastia* (emphasis added) (Ex. 2-31).

Finally another industry participant was reluctant to conclude that cytopenias "always" precede leukemia (Tabershaw, Tr. 2546). The evidence is not conclusive. There has been no scientific study of leukemia and preceding pancytopenia resulting from low levels of benzene exposure. The current lack of a reproducible benzene leukemia animal model forecloses the use of experimental evidence. There is no agreement on prospective criteria for benzene-induced blood abnormalities. Therefore, the statement that non-malignant pathological changes always precede leukemia is essentially based on retrospective analysis. The fact that non-malignant blood changes may occur shortly (within a few months) after first exposure to benzene, while leukemia may appear as long as 10 years or more after initial exposure suggests that separate etiologic pathways may be involved.

A corollary issue related to preceding blood disorders is whether recovery from such abnormalities eliminates the risk of leukemia deaths attributable to benzene exposure. Rosen has stated that: "[w]hether reversing the early toxicity can prevent the development of more serious blood dyscrasias in some cases is open to question, but it is a definite possibility" (Ex. P.C. 26A, p. 4).

> Jandl has written: "In carefully studying other reports of long latent periods, or of any period between an initial aplasia and a terminal leukemia in which the patient was hematologically normal, I failed to find any well-documented example of complete recovery followed years later (despite abstinence from benzene exposure) by acute myelogenous leukemia" (ORC/Jandl, P.C. 34, p. 24).

Because of the lack of information with a suitably identified cohort followed for a sufficient number of years, it is impossible to make a determination whether or not these "recovered" workers are actually at increased risk of dying of leukemia. This uncertainty has been expressed in the conclusions in the Dow Chemical Company morbidity studies:

> The question that remains unanswered, because of the relatively small sample size of this study, is what is the probability that serious effects of benzene (such as leukemia) will appear years after first exposure and after a period of health surveillance during which no hematological abnormalities are noted (Dow/Fishbeck, Ex. 154, p. 19).

OSHA agrees with the caveat expressed by Dow, and therefore the benzene regulation is not predicated on reversal of blood abnormalities protecting against the development of leukemia.

Benzene-associated leukemia is frequently characterized by a long delay between initial exposure and the onset of disease. Sellyei and Kelemen report a case of subacute granulocytic leukemia in a patient 8½ years after starting to work with benzene (Ex. 2B-258). Hernberg reported a case of a 10-year period between initial exposure and the onset of leukemia in a women with normal interval blood counts who was exposed to benzene for a total of 6 months (Ex. 217-152). In 1974, a case of acute leukemia was observed in a woman who, following a benzene-induced anemia, was reported to have an exposure-free period of 14 years with almost normal blood counts (Vigliani and Saita, Ex. 2-50, p. 214). Infante et al. report a range of 2-21 years between initial exposure and death; all but one exceeded 10 years (Ex. 2A-272). Goldstein hypothesizes that if benzene-induced hematologic damage is expressed by an * * *

> abberration in the bone marrow producing a stem cell that is liable to a further mutagenic event, such an event could conceivably occur many years after the original insult. (Ex. 43B, p. 166).

The delay in the expession of overt disease is a characteristic of many other carcinogenic compounds. With regard to benzene, it has been documented that there is a relatively rapid decline in the incidence of leukemias following cessation of worker exposure to benzene. Aksoy has testified that after the substitution of other solvents for benzene, there has been a decline in the annual number of workers diagnosed with benzene-leukemia (Ex. 60, p. 3). Vigliani and Forni reported that there was a sharp decrease in the cases of chronic benzene poisoning after the use of benzene as a solvent was banned (Ex. 2-50, p. 214). These observations appear to be paradoxical in light of the latency periods also reported. However, Forni and Vigliani have noted that, occasional cases of acute leukemia with a long latency period may still be observed (Ex. 2-50, p. 215) and Aksoy, while reporting that no additional cases of leukemia among shoeworkers were diagnosed in 1976, noted that this did not preclude the development of additional cases in the future (Tr. 169).* The question of latency periods for benzene-induced leukemias has not been resolved and requires further investigation.

Another area of discussion is the question of identifying individuals who may be particularly sensitive to the hematotoxic effects (including the development of leukemia) of benzene. Several witnesses including industry participants generally expressed the view that there probably were differences in sensitivity (Sakol Tr. 228; Shaw Tr. 412; Snyder Ex. 54.2, p. 25, Thorpe, Eckard Tr. 2052; Furst Tr. 1791-42). It appears from the evidence that there are individuals in given populations who may, because of genetic factors and/or concurrent or prior exposure to other en-

* A short latency resulting from high exposures is another possible explanation.

vironmental agents, be especially sensitive to benzene-induced blood disorders.

Aksoy and his colleagues reported a possible familial link in benzene-induced leukemias in 5 of 40 workers indicating a possible genetic predisposition to benzene's harmful effects (Ex. 60, pp. 8-10). Also, Jandl on the basis of tentative data has attempted to identify a subpopulation with risk factors predisposing to increased sensitivity to benzene (ORC/Jandl, PC 34, pp. 43-44). These include:

a. Those between the ages of 16 and 30;

b. Those with prior exposure to benzene or exposed to radiation in excess of that required for diagnostic purposes, and;

c. Those with evidence of a history of other less severe myeloproliferative disorders such as remitted aplastic anemia, certain abnormal circulating blood cells, or those with persistent abnormalities in one or more blood cell types.

Other predisposing factors may include exposure to drugs or alcohol which may act to modify the metabolism of benzene. These postulated effects are not consistently observed or universally accepted by investigators. In his testimony, Shaw stated that there was no way to determine who is susceptible to benzene and who is not (Tr. 420). And despite "well substantiated information" concerning the increased sensitivity of certain groups to benzene, the International Workshop was unable to develop and provide specific guidelines on this matter (Ex. 17, p. 7). These sensitive individuals, interspersed among the working population, are certainly among those who are at highest risk of material impairment from benzene exposure. The size of this group is unknown. It is the purpose of this regulation (especially the permissible exposure level and detailed medical surveillance protocol) to not only minimize harmful effects

of benzene exposure, but also provide early diagnosis and treatment should such effects occur.

c. *Animal studies.* The wide variety of non-malignant hematological disorders observed in humans exposed to benzene which range from simple anemia, and leukopenia to aplastic anemia have been experimentally induced in animals. However, attempts to demonstrate the development of leukemia in animals exposed to benzene has met with less success. Until recently, a study by Lignac in 1932 was the only animal study known to OSHA in which leukemia has been observed in animals exposed to benzene. (Ex. 2-38). Fifty-four mice (28 females; 26 males) were given subcutaneous injections of benzene (0.001 ml in 0.1 ml of olive oil) for 17 to 21 weeks. Nine mice were initially excluded following intercurrent infection and an additional 12 were lost through atrophy of various organs, especially the spleen. Lignac attributed these 12 deaths to the size to the dose of benzene. Eight of the remaining 44 mice developed leukemia or Kundrat's lymphosarcoma and died 4 to 11 months after receiving the first injection. The absence of concurrent controls makes interpretation of the results problematic and uncertain. Failure to identify the mouse strain studied has frustrated efforts to independently confirm the findings.

Other studies have failed to reproduce Lignac's results. Amiel in 1960 utilized four inbred strains of mice and subjected them to the same experimental program outlined in Lignac's study. (Ex. 2-39). No leukemic or aplastic hemopathies were observed. Ward et al. administered benzene subcutaneously to a strain of mice which is known to be responsive to leukemogenic agents. (Ex. 2-40). A slight increase in the percentage of granulocytic leukemias was observed in the benzene-treated mice as compared with the controls; however, the authors viewed the increase as not statistically significant.

In a letter transmitted Aug. 9, 1977 to Eula Bingham,

Asst. Secretary of Labor, Nelson described preliminary results of an inhalation experiment using rats and mice (Ex. 178). Animals were exposed to benzene vapors 6 hours per day, 5 days per week for up to 2 years. Two possible leukemias were observed in a group of 40 strain CD mice exposed to 300 ppm. In one animal, elevated WBC counts were observed 193 days after exposure, with death following 3 days later. The autopsy findings were consistent with CML, a disease not known to arise spontaneously in this strain. The second mouse exhibited the presence of abnormal blast forms in the peripheral blood after 211 days of exposure and died 4 days later. Whether this finding indicates AML, a disease previously observed in this strain, or acute lymphoblastic or stem cell leukemia (spontaneous incidence about 4 percent) had not been resolved at the time the report was submitted.

One of the 40 rats exposed to 100 ppm benzene developed an elevated WBC count after 240 days of exposure with the cell counts continuing to increase slowly. Peripheral blood smears showed some immature neutrophils. This finding is compatible with a diagnosis of CML, a disorder which is relatively rare for the rat. However, a nonleukemic leukemoid process could not be excluded.

Nelson characterized the results of the study as:

> * * * slender evidence of the production leukemia. Nevertheless, despite the shakiness, we believe these results to be extremely suggestive and provide an urgent basis for intensive further study (Ex. 178).

D. *Conclusions.* Leukemia is a serious world-wide problem. In this country alone, approximately 20,000 adults die annually from this disease, and about 12,000 individuals develop and die from AML each year (ORC/Jandl, P.C. 34, p. 72). However, based on the published literature the number of AML deaths attributable to benzene exposure is unknown. In this regard, Goldstein states: "The incidence of leukemia appears to be a small fraction of all benzene-

induced hematotoxicity." (Ex. 54.B, p. 160). One reasonably complete 9 year follow-up study of 147 workers exposed to benzene, of which 109 displayed some degree of cytopenia, 1 case of leukemia was observed (Hernberg et al., Ex. 2-252). Dr. Jandl observes that, "* * * few patients with proven cases of acute myelogenous leukemia can be discovered in the American literature in the past 10 years * * *." However, the unusual number of erythroleukemias observed by Sakol at the Akron Pliofilm operation (Sakol, Ex. 61) indicates that there may be a severe underreporting of benzene-induced leukemias. Also, the relationship between initial leukemia and exposure to benzene may be less apparent than the benzene-induced cytopenias due to the substantial delay between exposure and manifestation of symptoms (Goldstein, Ex. 43.B, p. 160). Moreover, in many such instances the victim may be unaware of earlier exposure.

When case reports are derived from patients who are sufficiently sick to seek medical attention, the relative prevalence of leukemia is reported to be much higher. For example, in the 1976 report by Vigliani and Forni in which a total of 83 compensation cases of benzene toxicity were observed, leukemia accounted for 19 (Ex. 2-15).

Vigliani has estimated based upon available literature, that the number of cases of leukemia attributed to benzene exposure is "at least 150" (Ex. 2-49, p. 144). The document, "Benzene in the Work Environment", used to establish the German Occupational Standard, summarized over 250 reported cases of leukemia in individuals who had been chronically exposed to benzene. (Ex. 2-58). Jandl states there have been at least 250 cases of AML in the United States which are believed to be the result of exposure to benzene. (ORC/Jandl, PC 34, p. 103). It is impossible to extrapolate these published findings to either an absolute total or a relative incidence. Beyond the likely underreporting of cases, the incidence of benzene leukemia may be greater than previously recognized since many diagnoses were made

without results of marrow aspirates. Thus, peripheral pancytopenia may have been inaccurately labelled aplastic anemia when marrow examination might well have revealed acute myeloblastic leukemia, leukopenic or aleukemic leukemia, a type characterized by a decline in circulating white cells. (Vigliani, Ex. 2-49, pp. 143-4).

The evidence in the record conclusively establishes that benzene is a human carcinogen. The determination of benzene's leukemogenicity is derived from the evaluation of all the evidence in totality and is not based on any one particular study. OSHA recognizes, as indicated above that individual reports vary considerably in quality, and that some investigations have significant methodological deficiencies. While recognizing the strengths and weaknesses in individual studies, OSHA nevertheless concludes that the benzene record as a whole clearly establishes a causal relationship between benzene and leukemia.

The evidence indicating that relationship has been expanding and the internationl scientific community has increasingly acknowledged that worker exposure to benzene is associated with an increased risk for the induction of leukemia, in fact, today there is little dispute that benzene is a human leukemogen.

For example, in 1976 NIOSH stated:

> NIOSH considers the accumulated evidence from clinical as well as epidemiologic data to be conclusive at this time that benzene is leukemogenic. Because it causes progressive, malignant disease of the blood-forming organs, NIOSH recommends, that for regulatory purposes, benzene be considered carcinogenic in man (Ex. 2-5).

In a paper presented at the International Workshop, Brair wrote that:

> It is now generally recognized that benzene leukemia is a nosological entity (Ex. 34-5, p. 4).

Vigliani has observed:

> [F]rom the vast literature accumulating over the last forty years, the conclusion can be drawn that the clinical as well as epidemiological data are indicative of a strong leukemogenic action in man " * * (Ex. 2-49, p. 148).

Aksoy testified that:

> [T]here is overwhelming scientific evidence that benzens can cause leukemia in man (Tr-144).

> Other witnesses and commentators were in basic agreement with this conclusion: (Goldstein, TR-351, 389; Sakol, TR-316; Jandl, P. C. 26B. Addendum V, P. V. Tabershaw Tr 2545).

In 1971, the Senate of the Deutsche Forschungsgemeinschaft for the Examination of Hazardous Industrial Materials indicted benzene as a human carcinogen (See NIOSH Ex. 84A, p. 1). Two years later, Eckhardt, then Medical Director of Exxon Corp., stated,

> [t]he accumulated evidence in the literature leads to the inevitable [sic] conclusion that benzene is a leukemogenic agent, particularly in cases that have previously displayed a panmyelopathy. Although this had long been suspected, the data reported in the literature was not sufficiently convincing to establish the leukemogenic nature of benzene. However, the more recent observations seem to establish the association beyond a doubt (Ex. 84, B.2., p. 7).

Industry participants in the benzene rule-making did not, for the most part, challenge benzene's leukemogenicity. Rather, they argued that there is a threshold level for benzene and that, consequently, benzene is not a leukemogen at low levels. In support of this argument, industry cited several epidemiological studies purporting to demonstrate that an excess risk of leukemia is not seen in workers exposed to benzene at levels lower than 10 ppm. Although the epidemiological method can provide strong evidence of a causal relationship between exposure and disease in the

case of positive findings, it is by its very nature relatively crude and an insensitive measure. In the case of negative findings, the results are especially difficult to interpret for several reasons. One methodological artifact commonly observed is the failure to adequately define the composition of the study cohort. The fundamental premise of any epidemiological investigation of the potential relationship of occupational exposure to an agent and observed health effects is, in OSHA's view, a careful definition of an exposed cohort. As was pointed out above, many of the benzene studies cited by industry suffer from this design defect. Other factors, such as incomplete followup of workers who may exit the cohort and uncertainly as to the actual cause of death lead to further dilution of the reported results. The presence of a latency period exacerbates this problem: The long delay between exposure and manifestation of symptoms, compounded by the high mobility of our society make it medically and scientifically extremely difficult to identify workplace carcinogens. An additional difficulty arises from the apparent variability in individual sensitivity. Epidemiological study populations tend to be small and reaction to an etiological agent may not appear in the cohort, due to varying degrees of sensitivity. On the other hand, positive retrospective investigations suffer from these artifacts to a much lesser degree. For these reasons, it is OSHA's policy when evaluating negative studies, to hold them to higher standards of methodological accuracy.

As stated above, the positive studies on benzene demonstrate the causal relationship of benzene to the induction of leukemia. Although these studies, for the most part involve high exposure levels, it is OSHA's view that once the carcinogenicity of a substance has been established qualitatively, any exposure must be considered to be attended by risk when considering any given population. OSHA therefore believes that occupational exposure to benzene at low levels poses a carcinogenic risk to workers. The Agency, however, recognizes that not all individuals exposed to benzene will suffer harmful effects. The benzene record establishes that there may be individual effect levels. However, there is no way of ascertaining which workers in any exposed population are susceptible and to what levels.

OSHA further recognizes that determinations of carcinogenicity are normally based on animal studies, and when available, human evidence. OSHA acknowledges that, at the present time, there is no unequivocal animal model demonstrating the induction of leukemia. However, the lack of an animal model does not diminish the conclusive nature of human evidence demonstrating benzene's leukemogenicity.

OSHA acknowledges that there are many unresolved issues concerning the relationship between benzene exposure and leukemia:

Whether benzene is a co-carcinogen, a procarcinogen, etc.

Whether benzene exposure is causally related to induction of forms of leukemia other than AML and its variants.

Whether blood dyscrasias, such as aplastic anemia always precede benzene leukemia.

To what extent are leukemia deaths attributable to occupational exposure to benzene.

What factors identify a sensitive population.

These questions are on the frontier of scientific and medical knowledge and, given the mandate of the Act, OSHA cannot wait for answers while workers are exposed to this life-threatening substance. There is no doubt that benzene is a carcinogen and must, for the protection and safety of workers, be regulated as such. Given the inability to demonstrate a threshold or establish a safe level, it is appropriate that OSHA prescribe that the permissible exposure to benzene be reduced to the lowest level feasible.

4. *Chromosome studies.* OSHA has examined both the

original literature of benzene-induced chromosomal changes and the material contained in recent reviews of the subject (NRC Report, Ex. 2-4, section entitled: Chromsome Effects; Forni, Ex. 156.H and; Wolman, NYU Report Ex. 43.B, Chapter VI). Evidence derived from human studies together with similar results obtained from experimental investigation clearly demonstrates that benzene can induce visible damage to chromosomes in lymphocytes and blood-forming cells. For example, Tyroler noted that: "I think there is rather convincing evidence that the chromosomal aberrations are associated with exposure to benzene." (Tyroler, Tr. 3100; also see International Workshop, Ex. 17, p. 6). The effects may be manifested as numerical alterations and/or structural rearrangements of the chromosomal material and include additions or deletions of chromosomes, segments of whole chromosomes or chromosome sets, in addition to exchanges which result in morphologically aberrant chromosomes (Wolman, NYU Report, Ex. 43.B, p. —). Forni has observed that the aberrations produced by benzene exposure are non-specific and are similar to those produced by ionizing radiation. (Ex. 156.H). To what extent these events are detrimental to human health is not known.

A. HUMAN STUDIES

There are numerous reports on chromosomal evaluations in worker populations both with and without clinical symptomatology resulting from exposure. In general, these studies reveal that there are statistically significant increases in chromosomal damage in those occupationally exposed to benzene. The chromosome alterations have been classified as either unstable changes (i.e., fragments, dicentric, tricentric and ring chromosomes) and stable changes (i.e. abnormal monocentric chromosomes due to deletions, translocations, inversions and trisomies). Aneuploidy (abnormal chromosome number) and/or polyploidy (a multiple chromosomal set) have also been observed. The early reports focused on the examination of workers exhibiting benzene

hemopathy (a disease of the blood). As early as 1964 Pollini and Columbi published such a study. (Ex. 2-17). Examination of cultured bone marrow cells and peripheral lymphocytes showed increased frequencies of aneuploid cells and structural aberrations. A second study by the same group (Ex. 2-4, reference 50) of 4 patients with temporary or progressive blood dyscrasias revealed that the incidence of heteroploid (abnormal number) chromosomal patterns ranged around 70% both in the blood and in the marrow of each subject. The authors were, however, unable to establish a correlation between the duration and degree of exposure and either the frequency of chromosome aberration or the degree of toxicity. Other cytogenetic studies of subjects with benzene-related hemopathies have yielded similar findings (e.g. Forni and Moreo, Ex. 2-18 and 2-19, Sellyei and Keleman, Ex. 2A-258; Aksoy et al., Ex. 2-57; and Erdogan and Aksoy, Ex. 2A-192). Variables which make these case reports difficult to interpret and compare include; differential diagnoses, the use of lymphocytes artifically stimulated to grow in some cases and bone marrow cells in others; the occasional lack of "normal" baseline chromosomal breakage frequency; and the occurrence in some cases of pre-existing familial chromosome aberrations (Wolman, Ex. 43-B, p. 129). In spite of the limitations of these reports, Wolman has stated that some trends have been observed—additional chromosomes have been identified in several reports, tetraploidy (4 sets of chromosomes) or polyploidy were seen in some cases and in many instances an increased frequency of chromosome breakage was reported but not well documented. Wolman states that:

> the clearest picture of the relationship between benzene exposure and chromosomal changes emerges, not from experimental studies or reports of human disease, but from studies of occupationally exposed workers (Ex. 43.B, p. 130).

The National Research Council (Ex. 2-4) considers the 1969 study by Vigliani and Forni (Ex. 2-20) to be one of the

most systematic of this type reported. The results of cytogenetic analysis of 25 subjects who had recovered from benzene hemopathy were compared to the findings of controls matched for sex and age. In most cases, increased ratios of both stable and unstable chromosome aberrations were still present several years after cessation of exposure to benzene and/or recovery from poisoning, whereas the hematological analysis revealed normal blood counts in most cases. Follow-up cytological analyses of these subjects showed an overall decrease in unstable changes, and generally, a persistence or an increase in stable alterations. Other cytogenetic surveys of workers industrially exposed to benzene are: (Forni et al., Ex. 2-20; Girard et al., Ex. 2-40; Hartwich and Schwanitz, Ex. 217-129; and Vigliani and Forni, Ex. 2-14).

OSHA is also aware of several cytogenetic studies of workers chronically exposed to airborne concentrations of benzene probably less than 25 ppm. Several indicate an increase in chromosomal damage (Hartwich and Schwanitz, Ex. 129; Girard et al., Ex. 2-65 or 2-283, and Berlin et al. Ex. 2A-218) while others present negative findings (Forni, Ex. 156.H; Tough et al., Ex. 2-21B, and Burgatti, Ex. 2A-226).

B. EXPERIMENTAL STUDIES

The quantity of data available from experimental studies is less than that reported for exposed workers, but it provides additional corroborative evidence that chromosomal aberrations can be induced by benzene. An in vitro study utilizing cultured human lymphocytes, incubated with benzene, revealed that the frequency of chromatid-type aberrations increased with increasing dosages of benzene. It was further observed that the yield of dicentric and ring chromosomes induced by benzene damage was synergistically related to treatment with radiation. A high incidence of chromosomal damage has also been observed in cultured human leukocytes and Hela cells incubated with benzene

(Koizumi et al., Ex. 2B-298). In 1970, Philip and Jensen reported that rats acutely intoxicated with subcutaneous injections of benzene displayed increased rates of chromatid breakage in direct bone marrow preparations 12 and 24 hours after injection, followed by a return to normal cytogenetic findings at 36 hours (Ex. 2-23). It has also been reported that rabbits made pancytopenic by chronic exposure to benzene via injection exhibited a high frequency of both chromatid and chromosome aberrations, in uncultured bone marrow cells (Ex. 2-22). After reviewing the animal evidence, OSHA concurs with Wolman's following conclusion:

> [T]hat although it appears that exposure times in different species can induce increases in chromosome aberrations, there is no clear evidence for a dose-dependent response to benzene exposure (Ex. 43B).

C. DISCUSSION

While the record clearly demonstrated that benzene causes chromosomal aberrations, it is equally clear that there is no unanimity of opinion as to what the benzene-induced chromosome aberrations mean in terms of demonstrable health effects, especially the relationship of chromosome damage to the induction of leukemia. For example, the International Workshop concluded: "The implication of the finding of increased chromosome aberrations for the occurrence of benzene leukemia is still not clear." (Ex. 17, p. 6).

Whether these aberration are, in some instances, (1) causally-related to the development of leukemia, or (2) are secondary to the neoplastic state and therefore are epiphenomena of metabolic alterations resulting from abnormal growth is not known (Sandberg, Ex. 2-102).

There are several theoretical considerations and some evidence supportive of the first alternative: Some investigators view chromosomal damage as a mutational event or

an event which increases the probability of a mutation (e.g., Wolman, Ex. 43B, p. 126). As the induction or the maintenance of a neoplastic (cancerous) transformation results most probably from a somatic mutation, damage to chromosomal material may enhance the opportunity for such a cellular change to occur. Other interrelated hypotheses in support of a causal relationship between chromosomal damage and leukemia are:

(1) That benzene might induce various types of chromosomal aberrations and that leukemia might evolve in those cases where a potential leukemia clone with a selective advantage develops in response to benzene exposure (Vigliani and Forni, Ex. 2-14).

(2) That cells exhibiting chromosomal instability or imbalance may be more susceptible to transformation by a leukemogenic virus (International Workshop, Ex. 17, p. 6); or

(3) That chromosomal aberrations may lead to decreased immunological surveillance, and that in such instances, leukemia can develop if abnormal cell clones (some of which may be neoplastic) are not eliminated. In this context, Forni and Moreau reported a case of a benzene-induced leukemia in which both bone marrow and peripheral lymphocytes exed 47 chromosomes (1 more than normal) with the same karyotype, suggestive of clone formation (Ex. 2-18).

There are also several investigators who believe that at this time, there is insufficient evidence to establish a causal link between visible chromosomal damage and leukemia (Ex. 156.2). For example, Snyder has stated that:

> while exposure to benzene in sufficient concentration and for extended periods of time has been linked with both chromosomal aberrations and leukemia in humans, benzene-induced chromosome damage has been found in individuals who have not exhibited leukemia * * * (p. 22).

Additional evidence in favor of the non-causal relationship

nature between chromosomal damage and leukemia was presented by Jandl. He observes that exposure to several types of agents, not known to possess leukemogenic action, induce chromosomal abnormalities which may persist for months.

Sandberg cautions that no consistent karyotypic pattern has emerged for any type of cancer or leukemia and in about half of all cases of acute leukemia, some cases of chronic myelogenous leukemia and in almost all cases of chronic lymphocytic leukemia, no visible chromosomal alterations occur (Ex. 2-102). And also, Elkins feels that the evidence fails to establish a causal link between chromosome alterations and leukemia (Ex. 156C, p. 22-23).

Whether these gross alterations of chromosomes can be viewed as toxic or mutational events depends on the fate of the affected cell. If the alteration in the chromosomal material results in an inhibition of further cellular division, then in terms of its reproductive potential, the cell is dead and the damage inflicted may be classified as a toxic event. However, if the damage does not interfere with the reproductive ability of the cell, and the alteration is replicated, this may constitute a persistent gross mutation, "* * * a structural change in the genome which presumably alters cell function" (Wolman, Ex. 43.B, p. 126). In addition to structural and numerical alterations, benzene has been observed to induce chromosomal breaks:

> While breaks may be repaired and are not necessarily mutational events (in the sense of being inherited), each occurrence increases the probability of a structural aberration and, therefore of a mutation (Wolman, Ex. 43.B, chapter VI).

In viewing benzene as an agent potentially capable of interacting with the genetic material, several points should be made:

(1) All of the studies demonstrating benzene's "clastogenic" or chromosomal-damaging effect (Shaw, Ex. 2-94)

have apparently reported the effects in somatic cells only. In view of the wide distribution of benzene in the body, it is not unreasonable, however, to assume that given somatic chromosomal damage resulting from benzene exposure, that germinal tissue may also be affected. In her review of clastogenic substances, Shaw has stated:

> Because changes in the genes and chromosomes do not usually produce an immediate health hazard, they may go undetected for a lifetime or even for several generations. Yet, the human gene pool can become insiduously polluted (Ex. 2-94, p. 409).

(2) Despite the considerable evidence demonstrating benzene's ability to inflict visible damage to chromosomes, benzene has not manifested mutagenic activity when tested in various microbial assay systems (Kraybill, Ex. 84.B 19, p. 314).

(3) The finding of gross chromosomal damage in bone marrow cells clearly demonstrates that despite competing detoxification reactions (see: Olson, Ex. 149, p. 12) benzene, or a reactive metabolite, is able to overwhelm protective defense mechanisms and enter the uncleus of hematopoietic cells.

In summary, the evidence clearly demonstrates that benzene is capable of causing significant increases in chromosomal aberrations in somatic blood cells in the absence of clinical and/or hematological symptomatology. It is also clear that for man, no quantitative dose-response relationship has been established for these effects. It is OSHA's interpretation of these findings that chromosomal damage represents an adverse biological event of serious concern which may pose or reflect a potential health risk and as such, must be considered in the larger purview of adverse health effects associated with benzene.

V. Economic Considerations

In setting standards for toxic substances, the Secretary is required by section 6(b)(5) of the Act to give due regard

to the question of feasibility. Section 6(b)(5) mandates that final standards be set which most adequately assure employee safety and health "to the extent feasible, on the basis of the best available evidence" and further requires that, in the development of occupational safety and health standards, "considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws." While the precise meaning of feasibility is not clear from the Act, it is OSHA's view that the term may include the economic ramifications of requirements imposed by standards. The determination that OSHA has the authority to consider economic feasibility factors in developing standards has been endorsed by the courts. *Industrial Union Dept., AFL-CIO* v. *Hodgson,* 499 F.2d 467 (C.A.D.C., 1974); *AFL-CIO* v. *Brennan,* 530 F.2d 109 (C.A. 3, 1975). As pointed out by the D.C. Circuit Court of Appeals, Congress did not intend the Secretary to promulgate standards which drive entire industries or large numbers of employers out of business. On the other hand, "standards may be economically feasible even though, from the standpoint of employers, they are financially burdensome and affect profit margins adversely; further, the Court said, the concept of economic feasibility does not "necessarily guarantee the continued existence of individual employers." *Industrial Union Dept., AFL-CIO* v. *Hodgson,* supra, at page 478.

In accordance with the Secretary's position, it has long been OSHA's practice to analyze the economic feasibility of proposed standards where significant economic impact on employers covered by the proposals seem likely, to make such analysis available to affected parties for comment and subsequent hearing prior to issuance of final rules, and to invite the submission of other information on the economic impact and feasibility of proposed standards. In developing a final standard, therefore, OSHA evaluates the economic feasibility of the final standard on the basis of the informa-

tion developed by its own studies of the proposal and submissions by the public during rulemaking.

To assess the economic feasibility of the proposed standard for benzene, OSHA undertook an extensive study of the proposal's economic impact on various affected industries. This study was conducted for OSHA by Arthur D. Little, Inc. (ADL). (Ex. 5A, 5B). The ADL study has provided basic economic data for the evaluation of the economic impact of the permanent benzene standard on the major affected industries. Additional information for this purpose was obtained through OSHA's analysis and consideration of all other economic data, comments, arguments and testimony submitted at the benzene hearing, in pre-hearing comments and in post-hearing comments and briefs. On the basis of the best available evidence, therefore, OSHA has determined, as explained in detail below, that the permanent benzene standard is economically feasible.

Compliance Costs

Estimates of total costs of compliance with the permanent benzene standard for the major affected industries studies are as follows: First year operating costs for all industries combined are estimated by OSHA to be approximately in the range of $187 million to $205 million, recurring annual costs are estimated at approximately $34 million and investment in engineering controls is expected to be approximately $266 million. Estimates of these costs for various individual industry sectors are analyzed below. As that analysis reveals, the greatest economic impact of the standard falls on the larger and more stable industries, such as petroleum refining and petrochemical production, which can readily absorb the costs or shift them forward to consumers. No testimony was offered by these industries that the proposed standard for benzene would imperil their existence. Even the higher projection of some costs by the American Petroleum Institute and other participants would

not raise any serious question concerning the economic feasibility of the standard or the ability of the regulated industries to bear the additional costs.

The benzene standard, in its final form will require all industries that produce or use benzene, petrochemicals, products and services involving the use of solvents derived from petroleum, as well as production of crude and refined petroleum products, and primary distribution of gasoline, to undertake an initial determination of the extent to which their employees are exposed to benzene. The results of the initial exposure measurements will determine the types of activities each firm will be required to take to comply with the provisions of this standard. Where exposure measurements are below the action level (0.5 ppm), firms will have to provide information and training in the hazards related to benzene to their employees, comply with the labelling requirements, and retain the records of initial measurements. These compliance activities account for the entire first year operating costs for many of these industries. Firms with exposure levels above the action level will incur additional first year costs for monitoring and medical examination programs. Finally, those firms with exposure levels above the permissible exposure level will have additional first year costs for installation of appropriate engineering and work practice controls, and for respirators. It is assumed that engineering controls are all installed in the first year and reduce exposure levels to below the permissible exposure limit. However, those firms with continuing exposure measurements above the action level will have recurring annual costs for monitoring and medical surveillance. Regardless of the airborne exposure measurements, employees in operations with potential exposure to eye or repeated skin contact will have to be provided with appropriate personal protective equipment. Thus, some firms and industries will have higher and more sustained cost burdens than others.

OSHA's estimates of costs for compliance with the final standard differ from estimates of the proposal's compliance costs in part because the standard in its final form differs from the proposal in areas which significantly impact on the cost of compliance. ADL estimated the proposal's compliance costs for 20 industry sectors engaged in benzene production (petroleum and coke), petroleum refining, chemical processing, benzene transportation, and other industries, such as rubber manufacturing and laboratories (ADL, Vol. 1, Ch. 5). ADL provided detailed cost estimates for each industry and for each compliance activity required by the proposal. Total costs for all surveyed industries were estimated by ADL as follows: First year operating costs were approximately $124 million, recurring annual costs were approximately $74 million, and costs for implementation of engineering controls were approximately $267 million. In developing each of these estimates, ADL used the control with the least cost as the basis of their calculations. In other words, where alternative methods of compliance are available to employers in an industry, and indeed may be more attractive to employers, the higher cost method was considered an optional process improvement, and only that portion of its total cost required to produce compliance was allocated to compliance with the proposed regulation (ADL, Vol. 1, pp. 5-3). Additionally, ADL assumed compliance with the previous OSHA regulation (29 CFR 1910.1000, Table Z-2) requiring an exposure limit of 10 ppm TWA and a ceiling limit of 25 ppm, thus assessing to the benzene proposal only the incremental cost associated with moving into compliance with the proposed permissible exposure level from the previous exposure limit.

The ADL costs covered 24,312 facilities and 196,875 estimated exposed employees (ADL, Ex. 5A, Table 5-1, p. 5-2). Costs were estimated for the required compliance activities of monitoring, medical surveillance, respirators, personal protective equipment, training, signs and labels, and recordkeeping. Distribution of costs varied from sector to sector

depending on such variables as the number of exposed workers who would require monitoring and medical surveillance and the estimated effectiveness of engineering and work practice controls. OSHA has examined the methods used by ADL to determine the costs for each provision of the standard and, in the absence of substantially contradictory testimony and alternative methods from affected industries, the approach of ADL has been largely adopted by OSHA in estimating the costs of compliance.

Based on all the evidence on the record, OSHA has estimated the cost of compliance with the benzene permanent standard for approximately 157,000 facilities and approximately 629,000 exposed employees.

Monitoring

As a basis for OSHA's estimates of compliance costs, OSHA has utilized for many industries ADL's sampling protocol for determining monitoring costs. ADL's protocol was designed to provide an initial exposure profile and characteristic sampling program.

ADL's representative explained that the protocol was intended to be representative, but that it might not fit each plant exactly and costs might be higher if the number of exposed workers in an industry, or those exposed above the permissible limit, were higher. (See Tr. 477-484, 522-526, and 592-595.) The derivation of the sampling base further explained in ADL's post-hearing submission as follows:

> The vast majority of facilities which must comply with this regulation are typified by twenty-four hour per day continuous processes representative of petrochemical operations. It was proposed to initially sample 50 percent of all exposed employees. However, the three shift nature of these operations and the commonality between worker exposures by job category between shifts indicated that sampling results from one shift could be properly interpreted as being representative for all shifts. Therefore only ⅓ of the exposed workers

should be sampled. Multiplying ⅓ × ½ equals ⅙ of the exposed employees who must be monitored. (Post-Hearing 15E)

OSHA recognizes that these assumptions may not portray exactly the monitoring pattern of employers within other industries. It is OSHA's view, however, that the monitoring scheme as described is a reasonable basis for estimating the cost of compliance with the monitoring requirements of the final standard.

In estimating the percentage of employees within each exposure category—i.e., above the permissible exposure level, between the action level and the permissible exposure limit, and below the action level, OSHA has used varying assumptions based on exposure data, where available. For the major portion of the covered industries, OSHA has accepted ADL's estimate that 20% of the exposed employees are above the permissible exposure limit. While there may be some variations in actual percentages at individual plants, industry witnesses offered no alternative approaches to estimating the number of exposed employees above the permissible exposure limit. Determination of the percentage of employees in each of the two exposure categories below the permissible exposure limit was based to the extent possible on record evidence of exposure. Where such evidence was not available, it was assumed for cost calculation purposes that one-half of the employees were exposed below the action level and one-half were exposed between the action level and the permissible exposure limit. Use of this distribution of exposed workers, however, does not imply that OSHA believes it necessarily represents actual exposure profiles for all industries; it has been used only to provide some basis for estimating approximate compliance costs and assessing the economic impact of the standard on these industries. OSHA has therefore, relied on the best available evidence as to likely exposure patterns in determining that its sampling protocol reflects typical industry conditions, provides a uniform estimation method enabling

inter-industry comparisons to be made, and yields reasonable approximations of the cost impact of the monitoring program.

OSHA has utilized the ADL methodology for calculating monitoring costs. There are, however, significant differences in total monitoring costs as a result of changes in the monitoring requirements of the final standard. The elimination of the proposed percentage exemption expands the number of employers covered by the standard and the number of employees affected. Cost estimates for compliance by employers using liquid mixtures containing less than 1% benzene were not given in the ADL study. However, inclusion of an action level in the standard, below which no regular monitoring or medical surveillance is required, should minimize the economic impact of the permanent standard. This is especially true since the proposal would have lowered the percentage exclusion to 0.1% after one year, and would have imposed periodic monitoring and medical surveillance of employees in these operations with any amount of exposure to benzene. Furthermore, it is anticipated that a significant number of operations utilizing mixtures with less than 1% benzene will be below the action level, in which case only initial monitoring must be conducted.

The introduction of an action level decreases for individual employers the cost of compliance for the monitoring activities. The proposal required quarterly monitoring where exposures were at or below 1 ppm. The final standard requires initial measurement to determine exposures but requires no further monitoring where exposures are below 0.5 ppm (unless a redetermination of exposures is necessitated by specific changes). As a result of this change in the monitoring requirements, some employers, who would have been required to monitor employees quarterly, will now only need to conduct initial measurements. Initial measurements it is estimated will cost approximately $109 million for all

industries combined. However, the actual cost will be substantially below this, inasmuch as the standard allows employers who have conducted initial monitoring, pursuant to the benzene guidelines or the emergency temporary standard, to utilize those measurements in order to initially determine employee exposure; and the benzene record indicates that many employers have conducted these measurements.

Medical Surveillance

The final standard, unlike the proposal, requires medical surveillance only of those employees whose exposure is at or above the action level. Moreover, the standard provides for twice yearly medical exams rather than quarterly exams. ADL has estimated the annual cost for routine medical surveillance as approximately $207 per employee annually, (Vol. II, App. C). This figure included employer and employee time, physician charges and laboratory fees (Vol. II, C-7).

Since routine medical surveillance is required by the permanent standard semi-annually rather than quarterly as contemplated by the proposal, OSHA has adjusted the ADL medical cost per employee to reflect the reduction in the number of periodic exams and to remove from the periodic exams the cost of the reticulocyte count and serum bilirubin, which the permanent standard requires only as part of the initial baseline exam. OSHA has, therefore, estimated the cost of the first year medical surveillance, including the work history, as approximately $105.00 per employee and the recurring annual cost of medical surveillance is estimated as approximately $78 per employee.

The final standard provides for medical surveillance in addition to semi-annual routine blood testing. Where routine medical surveillance reveals an abnormal blood picture, the employer is required to refer the employee to a hematologist. Where emergency situations occur, the employer

is required to provide a urinary phenol test and, if urinary phenols are elevated, a repeat complete blood count (CBC); if the CBC reveals abnormalities then the employee must be examined by a hematologist. The cost of these non-routine examinations was not estimated by ADL since they would not have been required by the proposal. There is, of course, no certain way of determining the number of employees who will need examination by a hematologist. To calculate these additional costs, therefore, OSHA has assumed that 5% of all employees will have abnormal blood pictures and will be re-referred to a hematologist, and that the added cost will be $100 per referral.

Other Costs

Total costs for other compliance activities, such as engineering controls, respirators, training, and signs and labels have also been assessed. These costs are based essentially on the cost factors furnished by ADL since the ADL costs were generally accepted by industry participants.

Capital costs for engineering controls have been determined for industries with operations above the permissible exposure limit on the basis of the type of engineering controls available for the individual industry. Many of the industries covered by the benzene standard involve the storage and movement within a closed system of liquids containing benzene in various concentrations. Emissions occur at such points as pumps, pipe line joints, compressors, sampling points, and gauging stations (Vol. 1, 4-35). Engineering controls for these systems consist of replacing worn pumps and compressors with equipment specifically designed to minimize emissions, replacing gaskets to ensure tight fit of joints, welding joints, and the installation of automative gauging and closed loop sampling devices. Specific units of these systems have been costed by ADL and aggregate costs shown below are based on an estimated number of these units which are required for a typical plant.

To determine respirator costs, OSHA has used ADL's cost per employee for respirators (Vol. II C-8, 9). For personal protective equipment, which is required by the standard for employees who may be exposed to eye or repeated dermal contact with benzene, the cost of $13.16 per employee per year has been used. This cost includes the cost of gloves, apron, faceshield, and goggles (Vol. II, C-R). Training costs, which include costs for preparation, materials, employee's time, and instructor's time, have been estimated at $110 per facility plus $14 per employee (Vol. II C-II).

In calculating recordkeeping cost, OSHA has utilized the ADL cost factor (Vol. II C-12) for record maintenance but adjusted this cost to reflect the decrease in the records required by the final standard. In its testimony, AISI expressed the view that recordkeeping would require the addition of one record clerk per facility (Tr. 3165-317 I). However, the final standard significantly reduces the monitoring records and eliminates medical records for employees whose exposure is below the action level. Therefore, application of ADL's cost formula will give a reasonable approximation of the recordkeeping burden.

For most firms, a normal cost for labels has been determined on the basis of ADL's cost of estimate (Vol. II C-13). No cost has, however, been determined for signs. Detailed data on a plant-by-plant basis were not available to OSHA. Therefore, no costs for this compliance activity are included within the cost estimates shown herein. OSHA recognizes that these costs will occur but is of the opinion that they will be relatively small for all firms covered.

Compliance costs for the following industries have been calculated by OSHA using the compliance factors described above.

Petroleum Refineries

It is estimated that petroleum refineries will incur greater compliance costs than any other industry sector. This is

primarily due to the large number of refinery workers who are exposed to petroleum products, almost all of which contain benzene. There are 48 refineries engaged in the production of benzene and 275 refineries which do not produce benzene but maintain process streams with benzene concentrations.

At the 48 refineries which produce benzene, there are approximately 1,440 exposed workers. On the basis of the exposure data made available by ADL and industry witnesses, it appears that approximately 20% of these employees are exposed above the permissible exposure limit. OSHA has, therefore, applied the ADL sampling protocol and calculated costs on the assumption that initial measurement will show approximately 300 workers exposed above the permissible exposure limit. The remaining exposed workers were divided for cost calculation purposes. Capital investment to reduce exposure levels has been estimated at approximately $24 million extrapolating from a model plant analysis. This cost would be for replacement of seals and controls of leaks (ADL, E-1) and similar indicated improved maintenance and repair. No estimate is made for shut down time since it is anticipated that any controls including modifications of pumps and compressors, would be installed during normal down time (Tr. 536). OSHA does not concur in the API view (Scarborough statement p. 36-7) that additional down time is needed since normal maintenance procedures of highly flammable material require purging of lines, and replacement of seals, pumps, etc. First year operating costs for these refineries are estimated at approximately $600,000.

Cost estimates for the 275 refineries which do not produce benzene were based on API's and ADL's data as to 98,000 exposed employees (ADL, Vol. I, p. 419; add API reference for that number). ADL relied in part on the results of an API questionnaire which indicates a wide range of exposures from negligible to as high as 25 ppm. (ADL

pp. 4-16 to 4-17). API's witness indicated that exposures at refineries were very low with most below the proposed permissible exposures limit and many below the action level (Tr. 1467-1468). Other testimony indicates similar exposure patterns (Grospiron statement, pp. 4-6). The API post hearing submissions suggest that refinery workers move frequently from one post to another so that they are not exposed to hydrocarbon vapors for extended periods of time (API, PH5). Initial monitoring results showing 8 hour TWA measurements of 0.13 ppm and lower were cited by API (API PH 8-9). In the face of conflicting data of this sort, it was assumed that approximately 5,000 workers initially could be found to be exposed above the permissible exposure limit, that approximately 5,000 would be exposed at levels between the permissible exposure limit and the action level, and that the remaining 88,000 would be below the action level. This distribution indicates somewhat higher exposure levels than API's testimony suggests, but lower levels than the results of the API questionnaire survey might be construed to indicate and is, therefore, intended to be a reasonable estimate. Using this distribution, OSHA estimates first year operating cost for compliance to be approximately $12.8 million. It may be noted that approximately $2 million of the indicated first year cost is for exposure measurements. Since many refineries have apparently made such measurements, actual first year compliance costs may be substantially lower than the estimates listed herein.

The cost of capital investment in engineering controls is estimated to be $110 million, for control of leaks from seals and valves, control of sumps and other disposal areas, and control of other emissions associated with storage, transfer, and gauging activities. If it is assumed that application of engineering controls is highly effective in bringing all worker exposure to levels below the action level, recurring annual costs would decline to approximately $3.5 million. If, alternatively, it is assumed that as many as 5,000 refinery

workers may continue to be exposed at levels between the action level and the permissible exposure limit, recurring annual costs would be approximately $4.4 million. OSHA believes the latter assumption is indicative of the upper bound of these annual costs.

Coke Plants

Compliance costs related to the production of benzene as a byproduct of coking are associated with activities at the coke batteries and at light oil processing facilities.

There are some 65 affected coke producing facilities. ADL had estimated that there were approximately 17,000 employees potentially exposed to benzene at coke oven batteries. The American Iron and Steel Institute (AISI) challenged this number as being an underestimation of exposed employees. The larger figure of 24,000 workers exposed at the coke oven batteries has been used by OSHA as urged by AISI (Tr. 4635, 472-4). This was the number estimated to be exposed to coke oven emissions in the Economic Impact Statement for the Coke Oven Emissions Standard. It is probable that this constitutes an overestimate of workers exposed to benzene at the coke oven batteries since benzene emissions are expected to occur only during portions of the production cycle and not at all locations (ADL, PC, 15f, 15i).

The AISI number is used, however, to avoid all possible underestimation of compliance costs for coke oven batteries and to indicate an upper bound to the probable costs. On the basis of data supplied (Ex. 135, p. 4 and attachment), it is assumed that initial measurement of exposures will show all workers exposed to benzene concentrations below the action level. Even if this were not the case, OSHA believes that engineering controls required under the coke oven emissions standard would provide adequate control of benzene emissions. On this basis, the estimated compli-

ance costs are approximately $1.2 million for first year operating costs and $860,000 for recurring annual costs. Since employee exposure does not exceed the permissible exposure limit, no capital cost is indicated for compliance with the benzene standard at coke oven batteries.

There are 65 coke oven light oil facilities associated with the coke oven batteries. ADL estimated that 2,370 employees were potentially exposed at the derivative light oil facilities. AISI argued that this number should be 4,000 employees. Consistent with the reasoning followed to estimate the number of workers exposed at coke oven batteries, the number of workers exposed in the light oil byproduct areas has been estimated to be 4,000, the number used in the coke oven emissions study. Data provided by ADL and AISI indicate that a substantial percentage of these workers may be exposed to benzene above 1 ppm. AISI specifically argued that at least 50% of by-products workers are exposed above the permissible exposure limit (AISI brief, p. 95). Consequently, to avoid any possible underestimation of compliance costs and indicate the upper bound of such costs, it has been assumed that all exposed workers will be exposed above the PEL at the time of initial measurement. Using these estimates of exposure, estimated compliance costs are $5.6 million for first year operating costs. OSHA has assumed that, after the installation of engineering controls, all exposures will be between the action level and the permissible exposure level. Since a significant number of light oil plants are old, controls may not result in reduction of exposure to below the action level. AISI expressed the view that engineering controls for older plants might not be feasible (P.I. statement p. 19); however, it appears that this concern was for economic rather than technological reasons. Thus, recurring annual operating costs are estimated at $887,000 for training, labels and recordkeeping. Capital costs are estimated at $19 million for investment in engineering controls.

Petrochemical Industry

The petrochemical industry includes firms producing a large variety of products from petroleum feedstocks. Six petrochemicals, accounting for about 90% of domestic consumption (ADL, Ex. 5B-96) were analyzed separately by ADL (Ex. 5A, 6-18ff) but since the exposure patterns of each are similar and the economic impacts affect many of the same or competing markets, the costs of petrochemicals have been aggregated by OSHA. The industry sectors included are chlorobenzene, cumene/phenol, cyclohexane, dodecylbenzene, ethylbenzene/styrene, maleic anhydride, nitrobenzene. This follows the analysis provided by ADL and the cost estimates shown are based on ADL's data. Industry participants did not challenge these costs.

There are 92 facilities covered by this standard, with 2,760 exposed workers (ADL, Ex. 5A, p. 4-4). On the basis of the limited data available on exposure levels (Vol. 1, pp. 4-7; Table 4-8, pp. 4-12 ff), it was assumed that 40 percent of the exposed workforce is exposed to benzene levels below the action level, 40 percent between the action level and the permissible exposure limit, and 20 percent above the permissible exposure limit. On this basis, first year operating costs will be approximately $1 million. Capital investment for engineering controls will be approximately $20.9. Recurring costs will be approximately $118,000. Recurring costs include training, labels, and recordkeeping since it assumed that engineering controls will reduce exposures below the action level.

Bulk Terminals

Storage and discharge of gasoline, and other petroleum products at bulk terminals is included within the benzene standard.

It is estimated that there are 1,992 terminal facilities with 52,345 exposed workers. Testimony by industry wit-

nesses indicated that by and large, no terminal employees were exposed to benzene levels in excess of 1 ppm (Tr. 1469-70, 1472-73; Ex. 115A, 10, pp. 17-19). Using these indicators of possible exposure distributions, OSHA has estimated compliance costs for terminals on the basis of 5,000 workers exposed to benzene between the action level and the permissible exposure limit, exposure with all other workers below the action level. On this basis, first year operating costs would be approximately $5 million and recurring annual costs would be approximately $2 million.

It is estimated that there are 21,106 bulk plants employing 23,471 drivers who are potentially exposed to benzene at terminals (ADL, Ex. 5a). Again using the limited data supplied by API, it was estimated that as many as 2,300 of these workers would be exposed at levels above the action level but below the permissible exposure limit. Conversion to bottom loading on all trucks was projected to reduce all exposures to below the action level. One this basis, first year costs were estimated at approximately $17.9 million, recurring annual costs at $3 million, and capital investment at $51.5 million.

Oil and Gas Production

There are approximately 700,000 oil and gas wells in the U.S. and, since any crude oil or natural gas may be expected to contain benzene, all of these are covered by the standard. API indicated that the number of exposed workers is 74,000 and that exposure levels are below the action level (Ex. 115A, 4, Ex. 116). As noted in the section on technological feasibility, workers are normally exposed only intermittently and occasionally, and emissions are limited to points where leaks or spills occur (Galloway, API, Ex. , p. 116, pp. 4-5). Proper work practices and good maintenance can minimize these exposures. It may reasonably be inferred, therefore, that all workers are exposed to benzene levels below the action level. Compliance costs, estimated on the basis of the reasoning used above, are approximately $39.6

million for first year operations and $2.6 million for recurring annual operations.

In determining these compliance costs, OSHA has assumed 10 wells per facility in contrast to API's reference to each well as a separate facility. It is probable that even this computation overestimates first year and recurring annual operating costs, since the costing formula for initial measurements allocates substantial charges on a per facility basis, amounting for example to approximately 90 percent of first year costs. The estimated first year costs would be reduced by the amount appropriate for measurements already performed pursuant to the benzene guidelines or the ETS. Monitoring costs would further be reduced where exposures at one workplace are representative of exposures at another.

Transportation

Companies engaged in the transportation of benzene and benzene contaminated products are covered by the benzene standard. OSHA's costs analysis, therefore, covers the transportation by pipeline, marine tanker, barge, tank car and tank truck of benzene and benzene products.

The cost analysis for pipelines is based on approximately 3,000 facilities. This figure was furnished by an API witness (Scarborough) who testified that there were 3,000 pipeline facilities employing 12,000 exposed workers. A witness for Williams Pipe Line Company estimated that there are 17,000 exposed pipeline workers (Bailey). The Williams figures, however, may represent total employment, including administrative and clerical workers. OSHA has utilized the figure of 3,000 facilities in combination with the two estimates of exposed workers to yield a range of estimated compliance costs. On this basis first year operating costs are estimated to be approximately $2.7 million and recurring annual costs for personal protective equipment, training and recordkeeping approximately $800,000.

Since the standard does not require labelling of pipelines, no labelling cost is included. Neither have engineering controls been assessed since industry measurements indicate that all workers will be below the action levels (Bailey).

The number of affected tank car facilities (loading and unloading) was estimated by ADL to be approximately 100, with an average of one exposed worker per facility (Table 5-1). The exposures of these workers will be dependent on the quantity of the various benzene-containing products shipped through the facility, the methods of loading and unloading cars, and the effectiveness of efforts to avoid leaks and spills. Conditions are somewhat similar to other facilities at which benzene and benzene-containing liquids are stored and transferred. Following the sampling protocol used throughout this analysis, costs were assigned on the basis that 20 percent of the exposures are above the permissible exposure limit, 40 percent between the permissible exposure limit and the action level, and 40 percent below the action level. It should be noted that, since it was estimated that only one worker per facility would be exposed, monitoring cost were estimated on the basis of 100 employees monitored. Engineering controls are to be installed at these facilities that will effectively control benzene emissions, bringing the exposure levels of all exposed workers below the action level. On the basis of this reasoning, it was estimated that compliance costs will be approximately $215,000 for first year operations, $16,000 for recurring annual costs, and $200,000 for capital investment.

Analysis of tank truck facilities shows a pattern very similar to that for tank cars. The rationale just described yield the following estimates: 200 affected facilities, 200 exposed workers, first year operating costs approximately $428,000, recurring annual costs approximately $37,000 and capital investment $100,000.

Barges are used for the transportation of benzene from refineries to points of utilization. Barges also transport

various refined petroleum products primarily for discharge at bulk terminals. It is estimated that there are 480 employees and 240 barge facilities involved in the transportation of benzene. The record indicates that employee exposure during loading and unloading exceeds the permissible exposure limit (Ex. 5A, 4-24). For cost calculation purposes, OSHA has estimated that 20% of the employees are above the permissible exposure limit, forty percent are between the action level and the permissible exposure limit, and forty percent are below the action level. On this basis first year operating costs are calculated at $526,000, recurring annual costs are calculated at $95,000 and capital investment is estimated to be $420,000.

Laboratories

Barges and marine tankers are also used for the transportation of gasoline. The distribution of these exposures, however, appear to resemble those encountered during gasoline production and distribution. In that case, the average cost of compliance per employee in his transportation, loading and unloading operations would range from $100 to $750 per employee.

Benzene exposures occur in chemical laboratories where benzene and other petroleum-based solvents are used. Where careful laboratory procedures are followed, such as the use of properly functioning hoods and appropriate work practices, exposures should be very low. In order to estimate the range of possible costs, OSHA calculated the cost on the basis of two scenarios. One scenario assumes that 10 percent of the exposed workers are initially exposed above the action level but below the permissible exposure level. The second scenario assumes 5 percent of the exposed workers are initially exposed above the permissible exposure level, 10 percent are exposed between the action level and the permissible exposure level, and all others are below the action level. On this basis, first year operating costs range

from approximately $4.5 million to $10.9 million. Recurring annual costs would be approximately $2.4 million, if all workers exposures drop below the action level after the first year, which is expected as a result of appropriate controls and work plactices.

Rubber Products

The ADL study examined the potential for benzene exposure in plants manufacturing rubber tires and other products, such as belts, hoses, fittings, and coated fabrics. ADL identified 206 affected tire producing facilities employing 11,400 exposed workers. The study cited data indicating that exposure levels were generally in the range of 1-3 ppm and may be considerably higher (ADL, Ex. 5A, pp. 14-19; Tr. 4-20). Similar testimony was provided by Drs. Tyroler and Harris of the University of North Carolina based on their studies of benzene exposure in the rubber industry (Tr. 3083-3095). Both studies indicated that control of exposure could be achieved, reducing exposure levels to below the action level, by substitution of materials and enforcement of appropriate work practices, and that engineering controls would not be required (Tyroler, Tr. 3086). Compliance costs were estimated, therefore, on the basis of all exposed workers being exposed initially above the permissible exposure limit, and exposures reduced to below the action level after controls have been instituted in tire manufacturing plants.

First year operating costs were estimated to be approximately $15.8 million and recurring annual costs approximately $407,000.

The analysis of firms producing other rubber products was based on the same considerations of workers exposed and compliance activities. For these firms first year operating costs were calculated at approximately $18.1 million, and recurring annual costs at approximately $484,000 based on 197 facilities with 13,050 exposed workers.

Other Industries

There are a number of other industries in which benzene exposure will occur due to the use of solvents, containing benzene in the processes or products involved. OSHA has estimated the approximate level of anticipated compliance costs for 16 industries thought to be representative of the range of cost impact involved: Adhesives manufacture and application, paint manufacture and application, paint stripper manufacture and application, printing ink manufacture, and gravure printing, metal can production, manufacture of photographic equipment and supplies, production of motors and generators, commercial printing manufacture of folding paperboard boxes, paper mills, and manufacture of wood household furniture. Firms in these industries are relatively small, use similar materials, will have generally low exposure levels, and can effect control of all worker exposures to below the action level by substitution of materials and enforcement of good work practices. It is OSHA's judgment that most of the employees in these industries are exposed to benzene levels below the action level. However, some data in the record on employee exposures related to the use of these solvents indicate that some workers in particular industries may be exposed at higher levels. OSHA feels that the probable range of costs can be indicated by calculating the costs under two hypothetical exposure patterns: (1) If 10 percent of the exposed workers are exposed above the action level, but below the permissible exposure limit, and all other employees are exposed below the action level; and, (2) if 5 percent of the workers are exposed above the permissible exposure limit, 10 percent between the action level and the permissible exposure limit, and all others below the action level. Costs calculated in this way indicate that, in these industries, the first year operating costs will lie in the range of $2,000 to $3,270 per facility or $240 to $390 per exposed worker.

OSHA is aware that there are other industries where

employee exposure to benzene may occur. However, although an opportunity to present data and views as to the application of the benzene standard to all industry sectors was afforded, no submissions were made on behalf of these industries. In the absence of exposure and cost data, OSHA has been unable to calculate costs for those industries. In summary, OSHA finds that the economic impact of the final benzene standard will not be such as to threaten the financial welfare of the affected firms or the general economy.

Other Economic Impacts

In addition to assessing the compliance cost and economic feasibility of the proposed standard, OSHA evaluated the economic impact of the proposed standard on affected industries and the general economy utilizing the criteria of Executive Order 11821 (39 FR 41501) as amended by Executive Order 11949 (42 FR 1017), and related implementing instructions particularly Secretary's Order 15-75 (40 FR 54484). The evaluation of such impact was made a part of the economic analysis of ADL. The methods of evaluating these impacts and the conclusions reached were extensively discussed during the benzene hearing.

The portion of the ADL study was designed to show the economic effects of compliance with the proposed final benzene standard upon affected industries. OSHA believes that this analysis, as modified to reflect the changes made in specific provisions in drafting the final standard, adequately defines the economic impact of the final standard.

ADL's analysis was, as discussed further below, challenged by witnesses for AISI and API on the ground that it was not sufficiently rigorous. Neither AISI nor API questioning of the ADL costing methodology indicated serious disagreement with the data used. Nor did these witnesses offer any evidence tending to disapprove the conclusions reached by ADL, or suggest specific analytical procedures which, if followed, would clearly improve the

study and increase the accuracy of the findings. After careful consideration of each of the questions raised by these and other witnesses, OSHA has made minor modifications in some elements of the cost analysis, and has concluded that the evidence indicates that the economic impact of the final standard may be more widespread than that shown in the ADL study but less severe for the industries analyzed by ADL.

Impact on Energy, Critical Materials, and Other Macroeconomic Variables

The ADL analysis indicated that there would be no significant change in either the supply or demand sides of the markets for energy or critical materials.

Two economists testifying for API argued that these were important areas of potential impact improperly ignored by ADL (Scarbrough, p. 4-5 and Henderson, p. 6-7). Under questioning at the hearings, however, neither witness offered any data indicating that these effects would be significant or put forth any reasons to suggest that they would be. (Tr. 2225-2226, Scarbrough, and Tr. 2212-2214, Henderson.)

Impacts on Prices

The compliance costs identified in the cost analysis provided the basis for estimating the impact on prices, output and labor productivity. The indirect costs resulting from increases in the prices of benzene and products made from it were identified and included in the estimation of impacts on producers and consumers. Capital costs were amortized over 7 years at 10 percent to reflect a normal return on investment. ADL assumed that the price would increase in the long run by the amount of any increase in long run average cost, including the normal return to investment. This provides a reasonable approximation of maximum potential price impact, and OSHA considers it to be accept-

able where exact costs cannot be known and precise measurement of price changes is not feasible.

Impact on Prices on Output and Market Structure

Economic impact was judged on the basis of expected overall influence of price increases, product substitution, price elasticity of demand, market growth, volume of imports and exports, market concentration, and compliance cost differentials.

ADL reasoned that buyers of benzene will continue to purchase the same quantities after a small price increase, provided there are no economical substitutes for benzene and provided that they can pass the added cost along in the price of their products. If users of the end products reduce their purchases in response to the cost pass-through, then the industrial purchasers will change the mix of products they manufacture and buy less benzene. The elasticity of consumer demand in turn depends on whether consumers can substitute other goods of the same type for those whose prices increase as a result of the cost pass-through, and whether consumers reallocate their incomes to buy other kinds of goods and services while buying less of the ones whose prices increased.

The magnitude of the expected costs is such that the percentage change in consumer product prices would be very small. No income effect (reallocation of income) of any significance would be expected. Therefore, elasticity would reflect almost entirely the availability of substitutes, as ADL indicated, although this conclusion would be questionable if a large price change was anticipated. ADL's product-by-product discussion of the availability of substitutes for benzene and for the petrochemical products made from benzene showed clearly that in all major product lines substitutes were judged to be technically inferior and more costly, at best, and unavailable with present technology in many instances. (ADL, Ex. 5A, pp. 6-18 to 6-22.) Consumer

substitution was also judged to be sharply limited on the basis of the quality and cost of available substitutes. OSHA believes that the reasoning followed by ADL in this qualitative analysis is reasonable.

Using an estimate of relatively inelastic demand for benzene (elasticity = − 0.5 (ADL pp. 6-11) and an estimated price increase of approximately 1 percent, ADL estimated that demand for benzene would fall by approximately 0.2 percent (16 million pounds) in the short run and by approximately 0.5 percent (54 million pounds) in the long run for refineries and steel companies producing benzene. Since the demand for benzene is growing moderately, these decreases would represent a slight decrease in the amount of growth, rather than an absolute decline from current levels of production. Foreign trade accounts for only 5 percent of U.S. supply and is not expected to be a significant factor affecting domestic producers, considering the small projected change in price.

The price of benzene is determined by petroleum refiners, who supply 95 percent of the market. Since coke oven producers will incur higher compliance costs than the benzene producing refineries, they will be able to recover only part of their costs through price increases and will be adversely affected by the standard. It appears probable that some producers of benzene from coking operations will choose to sell their light oil to other firms rather than continuing to produce benzene (AISI). Similarly, some refineries now producing benzene may elect to change their product mix to eliminate benzene production. These decisions will be made by benzene producers on the basis of many factors affecting the profitability of benzene production and not on the basis of the impact of this standard alone.

No data were submitted in the hearings that provided a basis for estimating the number of firms that may eliminate benzene production. It was not contended, however, that any

producing firm will be forced to close or be forced into an unprofitable position as a result of the compliance costs associated with this standard.

Impact of Prices on Employment and Productivity

Since ADL projected no absolute decrease in total production of benzene, it did not project employment losses for benzene producers. API witnesses questioned this on the basis of their challenge of the analysis of demand elasticity, price change, and reduction of demand. (Scarbrough, pp. 24-25; Henderson) OSHA reasons, however, that if these elements of the analysis are acceptable, the conclusion that production employment will not decline is valid, although some reallocation due to structural changes in the industries may occur.

API also argued that increased labor cost resulting from compliance programs could lead to some substitution of capital for labor. (Henderson, p. 10) In its testimony, ADL pointed out that the productivity of both labor and capital would decline in the same order of magnitude and that this would indicate that substitution would not occur. (TR p. 584) ADL also submitted that the industry sectors in question are quite capital intensive and that for this reason, "it is not anticipated that the proposed regulation would have any observed effect upon the utilization rate for labor in these industries." (ADL post hearing. Ex. 15N)

OSHA recognizes that some decline in overall labor productivity may result from adding compliance personnel such as technicians and hygienists to the work force of benzene producers, although the direct productivity of production workers is not affected. This decline was estimated by ADL to be approximately 1.4 percent for coke producers and 0.6 percent for refineries (ADL, Ex. 5A, Table 6.5, p. 6-16).

Benefits

The legislative history and language of the Occupational Safety and Health Act, as distinguished from some other

environmental and safety legislation, clearly indicate that Congress has already arrived at a judgment concerning the balancing of cost and benefit, with the result that worker safety and health are to be heavily favored over the economic burdens of compliance. Specifically, Section 6(b)(5) of the Act provides that

> the Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws.

Thus, while feasibility is an appropriate consideration, the Secretary is directed to set standards which attain the "highest degree of health and safety protection for the employee * * *."

This does not mean, however, that a systematic evaluation of costs and benefits is not to be encouraged within the limits of the estimation techniques. In considering the issue of feasibliity in this rulemaking, as in others, OSHA has carefully evaluated the cost of compliance which may be incurred by the directly affected employers and their ability to comply. Additionally, OSHA believes that a standard for a substance which has been found to pose a cancer risk to workers, in this case benzene, must assure maximum benefit (i.e., prevention of serious illness or death), constrained only by the limits of feasibility.

There is general agreement that benzene exposure causes leukemia as well as other fatal diseases of the bloodforming organs. In spite of the certainty of this conclusion, there does not exist an adequate scientific basis for establishing the quantitative dose response relationship between exposure to benzene and the induction of leukemia and other blood diseases. The uncertainty in both the actual magnitude of expected deaths and in the theory of extrapolation from existing data to the OSHA exposure levels places the estimation of benefits on "the frontiers of scientific knowledge." While the actual estimation of the number of cancers to be prevented is highly uncertain, the evidence indicates that the number may be appreciable. There is general agreement that even in the absence of the ability to establish a "threshold" or "safe" level for benzene and other carcinogens, a dose response relationship is likely to exist; that is, exposure to higher doses carries with it a higher risk of cancer, and conversely, exposure to lower levels is accompanied by a reduced risk, even though a precise quantitative relationship cannot be established. In light of the uncertainties in this area of scientific knowledge, OSHA believes that it is required by prudence and by the statutory mandate to adopt a highly protective posture in considering the evidence for health benefits.

Various witnesses argue that cost benefit or cost effectiveness should be the primary criterion for regulatory decision. OSHA was criticized by industry participants for failure to consider what benefits would be derived from reducing the current permissible exposure level for benzene (API brief, page 92, 96; AISI brief, page 89, 97). The Council on Wage and Price Stability (CWPS) also suggested that OSHA estimate the incremental reduction in health risks which are associated with the reduction in employee exposure to benzene (Bosworth letter, 9/12/77, to Bingham).

Both CWPS and industry suggested ways in which this could be achieved. CWPS suggested that OSHA apply the

expected lifetime incidence rates of leukemia and the increased incidence rates revealed by the scientific studies to the benzene exposed population to derive the number of expected excess cases attributable to that exposure. An MCA witness, Dr. Wilson, assumed a dose response relationship and calculated that at the current exposure levels only one leukemia and one other cancer would be observed among the benzene exposed workers covered by the proposal every 6 years (Ex. 149-B). This witness further testified that the proposed standard would cost $300 million for every hypothetical life saved (Tr. 2750) and concluded as a result that the risk from benzene related deaths is comparable to many other socially acceptable risks.

An API witness contended that rational allocation of OSHA's resources required policies that utilize cost effectiveness as the primary basis for regulatory decisions. He further argued that OSHA should make an assessment of what risks exists from exposure to benzene at 1-10 ppm., which should then be compared with estimates of risks posed by other health hazards such as from cotton dust (Tr. 2157) as well as with the risk associated with other activities of society which he termed generally acceptable risks in order to determine whether the cost of the benzene standard is warranted.

In the face of the record evidence of numerous actual deaths attributable to benzene-induced leukemia and other fatal blood diseases, OSHA is unwilling to rely on the hypothesis that at most two cancers every six years would be prevented by the proposed standard. By way of example, the Infante study disclosed seven excess leukemia deaths in a population of about 600 people over a 25-year period. While the Infante study involved higher exposures than those currently encountered, the incidence rates found by Infante, together with the numerous other cases reported in the literature of benzene leukemia and other fatal blood diseases, make it difficult for OSHA to rely on the Wilson

hypothesis to assure the statutorily mandated protection of employees. In any event, due to the fact that there is no safe level of exposure to benzene and that it is impossible to precisely quantify the anticipated benefits, OSHA must select the level of exposure which is most protective of exposed employees.

We recognize that in view of the latency period usually associated with the induction of cancer, significant reductions in mortality may not be seen for many years. However, unless exposures are reduced now, OSHA believes that the mortality rate will not decline and employees exposed to benzene will continue to suffer excess mortality. Finally, it should be noted that this standard for employee exposure to benzene cannot be simply described as a reduction in permissible exposure from 10 ppm. to 1 ppm. as a daily average. The previous standard for worker exposure to benzene permitted daily exposures as high as 50 ppm. for a period up to 10 minutes and repeated exposures of 25 ppm., levels which are known to produce serious hazards of blood diseases.

In making judgments about specific hazards, OSHA is given discretion which is essentially legislative in nature. However, in setting an exposure limit for a substance like benzene, OSHA may not substitute cost benefit criteria for the legislatively determined directive of protecting all exposed employees against material impairment of health or bodily function. Where the health effectiveness of the alternative approaches are extremely uncertain and likely to vary from situation to situation, OSHA must adopt the compliance strategy which provides the greatest certainty of worker protection even if that approach carries with it greater economic burdens for the affected employers. In the case of the benzene standard, the evidence in the record indicates that the costs of compliance are not overly burdensome to industry. Having determined that the benefits of the proposed standard are likely to be appreciable, OSHA

is not obligated to carry out further exercises toward more precise calculations of benefit which would not significantly clarify the ultimate decision. Previous attempts to quantify benefits as an aid to decision making in setting health standards have not proved fruitful (41 FR 46742).

Based upon the foregoing and the record as a whole, OSHA finds that compliance with the standard (even if the higher cost estimates suggested by some participants are used) is well within the financial capability of the covered industries. Moreover, although the benefits of the standard cannot rationally be quantified in dollars, OSHA has given careful consideration to the question of whether these substantial costs are justified in light of the hazards of exposure to benzene. OSHA concludes that these costs are necessary in order to effectuate the statutory purpose of the Act and to adequately protect employees from the hazards of exposure to benzene.

VI. Summary and Explanation of the Standard

The following sections discuss the various issues raised during the benzene rulemaking proceedings, the individual requirements of the permanent benzene standard and the rationale and policy considerations underlying the provisions of the standard. In developing these requirements, OSHA has considered all the evidence in the benzene record. After consideration of all of this evidence, OSHA has revised and clarified, as described in detail below, certain provisions of its proposed benzene standard.[1]

Scope and Application: paragraph (a) This standard applies to occupational exposure to benzene in all workplaces in all industries where benzene is produced, reacted, re-

[1] For the convenience of the public, OSHA has included, as part of the title of each section of the summary and explanation of the standard, the particular paragraph of the standard to which the discussion refers.

leased, packaged, transported, handled or otherwise occupationally used, except for the agriculture industry. Thus, the standard applies to "general industry" as well as to the construction and maritime industries. By specific exclusion discussed in detail below, the standard does not apply to the sale, discharge, storage, transportation, distribution or use as a fuel of gasoline and other fuels, subsequent to discharge from bulk terminals. The application of the standard is further limited in that not all of the requirements of the standard will apply to every employer regardless of the conditions in his workplace. The permanent standard, unlike the emergency temporary standard and the proposed standard, incorporates an action level so that the specific provisions of the permanent standard that apply to any particular workplace depend upon the extent of employee exposure to benzene. Additionally, only the labeling requirements of paragraph (k)(2), (3), (4), and (5) and the training requirements of paragraph (j) apply to workplaces where the only benzene is contained in sealed intact containers.

The scope of the final standard has been significantly changed from the scope of the proposal and the emergency temporary standard. OSHA was faced with several alternatives in deciding on the extent of coverage of the benzene permanent standard and in achieving its objective of maximizing the protection afforded employees occupationally exposed to benzene while limiting the burden placed on their employers. Benzene, as pointed out earlier, is used in a vast number of operations in quantities varying from trace amounts in solvents to large amounts of pure benzene. Coverage of all workplaces where benzene is present would, of course, extend the protection of the standard to the greatest number of employees. It would mean, however, that workplaces where benzene is present only in trace amounts and potential employee exposure is minimal would be subject to the same exposure monitoring and medical surveillance requirements as workplaces where the potential for

high employee exposure exists. While this would satisfy that part of OSHA's objective of maximizing the protection afforded employees, it would fail to reasonably limit the burden placed on employers.

Proposed Percentage Exclusion

The proposal and the emergency temporary standard both would have exempted from coverage those operations utilizing liquid mixtures containing 1 percent or less benzene by volume. The proposal would have limited this 1 percent exemption to the first year of the standard after which period only liquids containing 0.1 percent or less benzene by volume would be exempted. The proposed percentage exemption was based on some indication that exposures resulting from the use of mixtures containing less than 1 percent benzene would generally be less than 1 ppm (42 FR 27453-4). It was also anticipated that the percentage exclusion would lead to a reduction of the benzene content in solvents or to substitution of other substances for benzene with the result that employee exposure to benzene would be reduced or eliminated. As a result of evidence developed during the benzene rulemaking, however, OSHA has determined that the percent exclusion cannot be supported on this basis. The benzene record indicates that there is no consistent predictable relationship between the percent of benzene in a liquid mixture and the resultant airborne exposure to benzene (Tr. 3120). Studies conducted by the University of North Carolina demonstrated that exposure levels varied considerably during various work operations utilizing liquid mixtures containing the same percent of benzene (Tr. 3090-3091). Support for the conclusion that a less than one percent benzene solution can result in exposures above 1 ppm is found in testimony suggesting that other factors than the percent of benzene in the liquid may be determinative of exposure levels. Thus, NIOSH testified that employees working with No. 6 fuel which contains only 0.1 percent benzene were exposed to levels as high

as 60 ppm under certain conditions of confined space, poor ventilation or elevated temperatures (Tr. 754). The University of North Carolina data also revealed that exposure levels in heavy duty tire spraying utilizing rubber solvents were 1.3 ppm when sprayed by the regular full time operator but reached 5.2 ppm and 7.3 ppm when sprayed by a substitute operator (Tr. 3093). This suggests that work practices are also determinative of exposure levels. To maximize protection of employees, it is necessary to reduce their exposure to benzene, to the lowest feasible limit. Since the percentage of benzene in a liquid is not in itself necessarily controlling of the employee's exposure level, the proposed percentage exemption, would not achieve this objective. Accordingly, the final standard does not contain a percentage exemption and thus applies to all liquid mixtures containing benzene regardless of the percent of benzene.

It is OSHA's view that the absence of a percentage exemption does not eliminate all incentive to reduce the amount of benzene in liquid mixtures. Where another substance is totally substituted for benzene, this standard will obviously not apply. Additionally, it should be noted that the inclusion of an action level will effectively limit the burden of this standard where employee exposure is found to be low because of its limited presence in a mixture.

Benzene Substitutes

In lieu of the percentage exception, OSHA considered the option of exempting from the standard certain benzene substitutes, such as toluene and xylene (although they may contain small amounts of benzene). An exemption of this type would encourage employers to discontinue the use of benzene and utilize a substitute in order to avoid the requirements imposed by the benzene standard. These substances themselves, however, do contain varying amounts of benzene and, as stated above, there is no evidence of a consistent direct predictable correlation between the amount of benzene and exposure levels. Thus, it was concluded that toluene and xylene, to the extent they contain benzene and result in benzene exposure, would be covered by the standard.

Action Level

OSHA recognizes that the lack of a percentage exemption substantially expands the coverage of the benzene standard to operations which may otherwise have been exempt. In many of these operations, exposure levels below the permissible exposure limit have already been achieved. To minimize the impact of the standard on those employers who have attained these low exposure levels, the final standard provides for an action level. This action level is a benzene exposure equal to one-half of the permissible exposure limit above which certain precautionary measures, such as periodic monitoring and medical surveillance programs must be conducted and below which only a very limited number of the standard's requirements will apply. Thus employees who have an initial exposure measurement below the 0.5 ppm TWA action level will not have to be monitored periodically. If the initial monitoring exposure measurement is below the action level, no further monitoring is necessary until such time as a redetermination may be required as a result of a process, control or personnel change. Furthermore, medical surveillance of individual employees whose initial exposure measurements are below the action level would not be required. Nor would regulated areas need to be established or engineering or work practices instituted or respirators provided. All other provisions of the standard, however, would apply and the employer would need to train his employees in the hazards of benzene exposure, to properly label his products and to maintain the record of the initial exposure measurement and, if any, the record of the redetermination measurement.

The adoption of an action level had been recommended by several participants to the rulemaking. NIOSH, recom-

mended that an action level for periodic monitoring and routine periodic medical exams be incorporated for the purpose of assuring that no employee is exposed above the permissible exposure limit (Tr. 749-750). Industry participants advocated a level which would trigger the periodic monitoring of employee exposure (Com. 24; Com. 72; P.C. 36 AISI brief p. 74, FT. no. 168). A need for an action level is also suggested by the record evidence that some minimal exposure to benzene occurs naturally from animal and plant matter (Tr. 749-750; 759-760). Naturally occurring benzene concentrations, it appears, may range from 0.02 to 15 parts per billion (Ex. 117, p. 1). Additionally, it was suggested by certain employers that their operations be exempted from the requirements of the standard because those operations involve only intermittent and low level exposures to benzene. The use of the action level concept should accommodate these concerns in all cases where exposures are indeed extremely low since it substantially reduces the monitoring of employees who are below the action level and removes for these employees the requirement for medical surveillance. At the same time, employees with significant overexposure are afforded the full protection of the standard.

In developing this regulatory approach to occupational exposure from benzene, OSHA considered the request of those participants to the rulemaking who pressed for exemption from the benzene standard of their particular operations.

Bulk Terminals

The final standards apply to bulk terminal operators but exclude exposure from gasoline, motor fuels and other fuels subsequent to the discharge from the bulk terminal.

During the rulemaking, bulk terminal employers requested that their gasoline operations be exempted from the benzene standard. Bulk terminals are the primary distribution facilities in the gasoline marketing network. A

bulk terminal is the first distribution point of gasoline after the gasoline is processed by the refinery. Gasoline products are transferred from refinery storage to the terminal by pipeline, tanker or barge (Comeaux statement, p. 11; A. D. Little, vol. II, D-35) and placed in larger storage tanks (Tr. 2353) at the terminal. Further distribution from the terminal is most commonly by tank trucks (Comeaux statement p. 11). The gasoline is pumped from the terminal storage tanks into the trucks and distributed directly to consumers, to retail outlets, i.e. retail service stations, or to other secondary distribution points. These secondary distribution points are smaller terminals (Tr. 476) referred to as bulk plants, which also distribute the gasoline by truck to ultimate consumers, such as farmers and small businesses, or to retail outlets. Final distribution of gasoline to retail service stations and to ultimate consumers is, therefore, by truck and either from a bulk terminal or a bulk plant (Comeaux statement, p. 11). Gasoline emissions occur at the storage tanks, at the tank trucks, and from leaks and spills, with the major emissions occurring when tank trucks are being loaded with the gasoline. The majority of terminal storage tanks are equipped with floating roofs which are effective in reducing storage emissions. Some tank trucks have bottom loading which reduces emissions during loading (Tr. 1294).

Participants in the benzene rulemaking argue that the exclusion of gasoline storage and distribution activities subsequent to discharge from the terminals results in an artificial distinction between bulk plants, which are not covered by the standard, and bulk terminals which are covered. (API P.C. 33, pp. 138-140; Comeaux, p. 12 Sexton p. 22). In support of this contention, industry furnished evidence that exposures at bulk plants were similar to exposures at bulk terminals (Ex. 115A-10; Sexton, p. 18; L.C. 4) and that bulk plants handle the same products, utilize similar handling procedures and use basically the same equipment as bulk terminals. From the technological standpoint, it also ap-

pears that several of the same types of vapor recovery systems can be utilized by both the bulk plants and the bulk terminals (Tr. 236). The major difference between bulk terminals and bulk plants, it was said, is a difference in the number of gallons of gasoline distributed (Sexton; Durham L.C. 4).

Although this description of bulk terminals and bulk plants suggests that there may exist some basis for treating bulk plants in a like manner to terminals, it does not necessarily follow that bulk terminals should be excluded from the standard. The question of what regulatory action should be taken with regard to bulk plants was, by specific notice issued prior to the benzene hearing (42 FR 32363), not an issue at the benzene hearing. This exclusion of post terminal gasoline marketing activities from the benzene rulemaking was not based on the absence of any hazard. Rather, as stated in its FEDERAL REGISTER notice, OSHA concluded that regulatory efforts to reduce workers' exposure to benzene released during the transportation, storage, distribution and sale of gasoline subsequent to discharge from bulk terminals should await the conclusion of the deliberations of the interagency (OSHA-EPA-NIOSH) task force which was actively considering those activities. (As pointed out in the preamble to the proposed benzene standard (42 FR 27453) certain phases of the downstream gasoline activities which have been exempted from the standard, involve additional hazards which may necessitate different protective requirements and the development of appropriate equipment control devices, and require that these downstream operations be handled in an integrated manner.) In the same notice excluding bulk plants as an issue at the benzene hearing, OSHA solicited data and comments regarding those distribution activities "in order to assist in the subsequent development of a proposal for this industrial segment." Therefore, OSHA has presently under consideration the question of what types of regulatory action to propose for the protection of bulk plant employees exposed to benzene. Pending this regulatory action, bulk plants and other post terminal operations will continue to be subject to the requirements of 29 CFR 1910.1000 and to meet the exposure limits of Table Z-2 of that section.

The exclusion of bulk plants from the notice of the benzene rulemaking precludes regulation of those facilities in this final benzene standard. Exemption of the bulk terminals which were covered by the notice of rulemaking, however, would remove from the protection of this standard those employees who are involved in terminal activities. Data from eleven companies indicate that they operate 892 bulk terminals employing 9,900 employees (Comeaux, p. 12). One company alone estimated that over four thousand of its employees were exposed to benzene in its gasoline marketing operations covered by the standard (Sexton p. 20-1). This same company indicated that most of its 924 commissioned agents and 1,014 jobbers handling its products alone would have employees exposed to benzene emissions during terminal activities. It is OSHA's view that benzene's carcinogenicity requires extending the protection of the standard to the greatest number of employees. Accordingly, OSHA deems it necessary to apply this benzene standard to gasoline storage and distribution operations at bulk terminals.

It is OSHA's view that application of the benzene standard to bulk terminal activities will not impose a great burden on bulk terminal employers. The record evidence indicates that the exposures at storage tanks and loading docks at the terminals, of at least some employers range between 0.2 and .41 ppm on an 8-hour TWA (Sexton Ex. 115-A, 10). These ranges are based on measurements taken during the loading of trucks with and without bottom loading equipment. Where employee exposure to benzene is below the action level, as in the case of the range of measurements cited above, the standard imposes a minimum burden upon the employer.

Non-Gasoline Petroleum Products and Activities

Industry participants further argued that exemption of downstream gasoline marketing operations discriminates against the non-gasoline phases of the petroleum industry, such as oil and gas production, pipelines, marine petroleum transportation, refineries and petrochemical facilities, because worker exposures and compliance costs are comparable (API PC 33, pp. 140 ff, Com. 29). Crude oil and natural gas producers further argued for exemption of their facilities because conditions at their facilities—namely, open air workplaces, widely scattered employees, the transient nature of their workforce and essentially no exposure to benzene, made compliance burdensome (Com. 33). As stated above, the need to protect the many workers involved in the non-gasoline activities necessitates the inclusion of these activities in the benzene standard. Furthermore, by virtue of the action level concept, these very factors cited by the oil and gas producers will substantially mitigate the burden of the permanent standard on employers.

Air transport participants using aviation fuels, such as kero jet, argued that non-gasoline aviation fuels be included in the gasoline aviation marketing exemption. OSHA agrees. OSHA recognized, in its preamble to the proposed benzene standard (42 FR 27453), the special need to coordinate the Federal Government's efforts in reducing benzene exposure in certain aspects of the distribution of gasoline and other motor fuels. The joint OSHA-EPA-NIOSH task force, consequently, has under consideration the matter of non-gasoline motor fuels. Besides kero jet, there are other types of motor fuels, such as diesel fuels, which raise the same issues of control as gasoline. There may be other motor fuels containing benzene on which OSHA does not have data. OSHA is conducting its own review of gasoline and has solicited information from the public on gasoline (42 FR 32263). It is, therefore, OSHA's intention to determine the regulatory action to be taken on non-gasoline motor fuels after review of the data and recommendations of the joint Federal task force and evaluation of the information furnished in response to OSHA's notice on gasoline. For these reasons, OSHA has exempted from the permanent benzene standard the storage, transportation, distribution, dispensing, sale or use as a fuel of all fuels (including gasoline, jet fuel, and diesel fuel) subsequent to their discharge from bulk terminals.

Closed Systems

Some participants requested exemption from the standard for workplaces where benzene is present solely in closed systems. The record evidence, however, indicates that closed systems frequently develop leaks, and that it is the amount of the solvent exposed to air (Tr. 3111-3) which, among other variables, is a major determinant in the degree of exposure. Accordingly, OSHA has retained coverage of closed systems in the final benzene standard. However, in the absence of leaks, exposures from closed systems should be below the action level and the impact of the standard in such operations should be minimal.

Laboratories

Still another segment of industry requested an exemption from the benzene standard. Many comments requested that research facilities in both industrial and academic laboratories be exempted from the benzene standard (Com. Nos. 14, 20, 57, 62, L.C. 12, L.C. 13) particularly where the permissible exposure limit is not exceeded (Com. 56, 58). Some comments suggested that separate requirements be developed for laboratory use of benzene (L.C. 12, L.C. 13). These requirements could include mandatory use of hoods (L.C. 9, Com. 21) of a specified velocity (L.C. 8, Com. 18) and periodic medical surveillance (Com. 18, 28, 29, 64, 70); annual inspection in lieu of monitoring (Com. 28); written safety rules (Com. 18) and container labeling (Com. 39) were also

suggested. In the alternative, it was suggested, OSHA should promulgate separate regulations for all chemicals used in laboratories (L.C. 12, L.C. 13), since laboratories use a variety of chemicals, and compliance with separate regulations for each chemical, it was argued, would be burdensome (Com. 58).

The requests for exemption from the benzene standard or for special treatment of laboratories were largely based on the view that there exists a lesser, or slight, risk of exposure to benzene for laboratory technicians. In support of this contention, laboratories pointed to the manner in which they use benzene. Laboratories, it was stated, generally use small quantities of benzene at a time (Com. 10, 28, 38). One laboratory reported that sometimes a sample is dissolved in only one ml of benzene (L.C. 2). That laboratory estimated that an individual laboratory technician, who analyzed 25 samples per day, 7 days a week, would use less than four gallons of benzene a year (L.C. 2). When not in use, benzene is stored in closed containers (L.C. 1).

The argument that laboratory technicians are trained in the hazards of chemicals was also made to support the view of lesser risk. One laboratory reported that it conducted blood tests every four months for twenty years of its technicians, and found no problem (Com. 4). Another reported that in thirty-five years, none of its employees developed leukemia even though exposures in the laboratory were between 1 and 20 ppm (Com. 31).

Another reason advanced for exemption or separate treatment of laboratories was the burden and cost of implementing exposure monitoring, engineering controls and medical surveillance (Com. 4, 5, 10). One industry comment argued that responsible research and quality control laboratories normally provide and encourage annual physical examinations that include the essentials of the proposed medical surveillance program (Com. 38).

OSHA has determined that applying the provisions of this benzene standard to laboratories is consistent with OSHA's responsibility to protect the health and safety of workers. The record indicates that exposure levels in laboratories vary greatly. While monitoring samples of one laboratory indicated levels of only .01 ppm (Com. 28), others indicated levels as high as 20 ppm (Com. 31; Ex. 39-3). Furthermore, it appears that protective measures vary from lab to lab (Tr. 3157). One chemist, who worked frequently and for several hours a day with benzene during his six years in a research lab that he described as "one of the most prestigious research institutions in the country," testified that employee exposures were not measured, hoods were not used, and there was no medical surveillance program (TR 3492-6). Moreover, there does not appear to be any firm basis to believe that training alone in handling of chemicals adequately protects all laboratory employees from the hazards of exposure to benzene.

Based on the above evidence, OSHA believes that laboratory employees are exposed to the leukemogenic hazards of benzene and, therefore, must be covered by this standard. OSHA does not subscribe to the view that laboratories should be exempted from the benzene standard and that protection for employees exposed to benzene should await promulgation of separate regulations for all chemicals used in laboratories. OSHA is not currently developing a laboratory standard, and the result of exemption of laboratory workers from the benzene standard would, consequently, deprive them of the necessary protection against the hazards of benzene exposure for some time to come. Furthermore, the provisions of the standard relating to methods of compliance are performance oriented and, therefore, will encompass the suggested special requirements for laboratories. For example, the requirement that the employer institute engineering controls and work practices could be met by laboratories in many instances through the use of properly designed hoods. Also, the inclusion of an action

level will minimize the monitoring and medical surveillance requirements in laboratories where employee exposure measurements indeed are low.

Although OSHA has not included special provisions just for laboratories, the provisions of the standard accommodate several of the suggestions of the participants, as noted above. Those laboratory operations where benzene exposure levels are at or below the action level will need to be monitored only initially, and medical surveillance of employees engaged in those operations will not be required. When benzene is sealed in containers, the laboratory employer will be required only to train his employees in the hazards of exposure to benzene, and assure that the container is properly labelled, and provide protective clothing where necessary.

Coke Oven Batteries

Steel industry participants requested an exemption from the benzene standard for coke oven workplaces which are covered by the coke oven emissions standard. Although coke oven emissions at coke oven batteries are regulated by § 1910.1029, it is OSHA's view that there is a need to apply to these workplaces the requirements of the benzene standard, as well. The coke oven standard regulates the benzene soluble fraction of total particulate matter present during the carbonization of coal for the production of coke to protect workers from the risk of developing cancer of the lung and urinary tract. The coke oven standard, however, was not designed to protect coke oven employees from the hazards to the hematopoietic system which can result from exposure to benzene. Benzene exposure can occur from leaks in the ovens or in the collection system or from residual vapors left in the ovens when they are opened and the hot coke is pushed out (Little study, B-21). Accordingly, in order to protect workers from the hematopoietic hazards presented by exposure to benzene, OSHA has concluded that inclusion

of all coke oven workplaces in the benzene standard is necessary.

The coverage of coke oven workplaces by both the benzene and the coke oven emissions standard does not create a conflict. OSHA believes that the engineering controls required by the coke oven emissions standard will, in all likelihood, reduce exposures to benzene below the action level. In such a case, the benzene standard will impose on coke oven workers only the burden of conducting initial measurement, retaining a record of that measurement, and the training of employees in the hazards of benzene.

Sealed Containers

The final standard applies only to the labeling requirements and the training requirements to the storage, transportation, distribution and sale of sealed, intact containers. This is a change from the proposed standard, and the emergency temporary standard which would have applied all the requirements of the benzene standard although benzene were "present" solely in sealed containers. The change in the final standard was made in response to comments to the effect that closed containers of benzene pose no threat of exposure to employees (Com. 10). Participants in the rulemaking pointed out that coverage of closed containers would result in employers being required to monitor exposure and make medical surveillance available to employees, such as maritime employees occasionally handling small quantities of benzene in breakbulk form (i.e., drums or packages) (Com. 35), employeees of receiving docks and warehouses, and employees involved in inter- departmental transfers of the containers (Com. 28). Additionally, such coverage would also apply the requirements of the benzene standard to employees of retail stores that sell products containing benzene.

Most participants requested exemption of closed containers (Com. 10, 28, 35) without distinguishing between

closed and sealed containers. A state agency comment, however, suggested that only "sealed" containers be exempted (Com. 67). OSHA concurs in the view that properly closed containers do not present a health hazard to employees which warrants application of the monitoring and medical surveillance requirements. OSHA, however, is concerned that containers may, after being opened, be closed in such a fashion as to expose employees to a hazard. For this reason, OSHA has adopted the suggestion that the exemption apply only to *sealed* containers, intending by the use of that term to exempt only containers of benzene which are closed in such a manner as to contain the benzene vapors. However, since sealed containers may, during handling, develop leaks (Tr. 3051-2) and thus expose employees to the hazards of benzene, the exemption is further limited to intact containers. Therefore, where the breakage of the container occurs, employers will be required to monitor and to comply with any other applicable provisions of the standard. To assure that all employees are aware of the hazardous nature of the contents of the containers they are handling and because at some point in downstream occupational activities the containers will be opened, the standard applies the training and the labeling requirements to sealed containers. Finally, it should be noted that the regulation of sealed containers in this standard is consistent with that in other carcinogen standards; §§ 1910.1003-1910.1016 exempt sealed containers from their requirements, except for labeling and transshipment.

Definitions: paragraph (*b*). The standard contains some appropriate definitions. The purpose of providing definitions for key terms is to clarify the intent of those terms as used in the substantive provisions of the standard. All of the definitions of the proposal have been retained in the final standard.

A new definition has been added to those contained in the proposed standard. This is the definition of "Action level."

Action level is defined as a concentration of benzene of 0.5 ppm over an 8 hour workday. Industry participants recommended that monitoring be conducted only where exposure exceeds the permissible exposure limits (PC 36, AISI brief, p. 74). OSHA does not agree. It is generally acknowledged that worker exposure to airborne emissions can vary from day to day in a random fashion. This variation in levels is unavoidable; it is only minimally connected to the precision and accuracy of the method of measurement and does not include variations due to wind, temperature and other environmental factors.

Therefore, even though individual measurements of exposure levels may fall below the permissible limit, some possibility exists that on unmeasured days the employee's exposure may exceed the permissible limit. Thus, the concept of an action level provides, statistically, a means by which the employer may assure himself that his employees will not be exposed to benzene over the permissible exposure level (PC No. 14g, p. 5). In view of these considerations and in order to provide a greater degree of employee protection, OSHA has incorporated in the permanent benzene standard an action level of 0.5 ppm.

For those employees whose exposure level is determined by initial monitoring to be below 0.5 ppm, the employer need not do any further monitoring unless a redetermination of exposure is necessitated because of a process, control or personnel change. For these employees, moreover, the employer is not required to provide medical surveillance. The employer, however, must train these employees, label his benzene products, provide protective clothing where necessary, and retain a record of the initial determination and, if any, record of the redetermination measurement.

Employees whose exposure measurements are above 0.5 ppm, but below 1 ppm must be monitored quarterly and provided with medical surveillance. Where exposures are above the action level but below the permissible exposure

limit the requirements for regulated areas, methods of compliance and respiratory protection do not apply but the employer must comply with all other requirements of the standard.

Those employees whose measurements are above 1 ppm must be monitored monthly. All the provisions of the standard, moreover, apply where employees are exposed above the permissible exposure limits.

OSHA has, as suggested by some participants (Com. 46), clarified the definition of benzene to include solids which contain benzene. Some comments suggested that benzene be defined as commercial or high grade benzene (Com. 48, 59, 76). OSHA has not adopted this suggestion because of record evidence to the effect that low concentrations of benzene do not necessarly result in low exposures. Other comments suggested that a definition of benzene exposure be included (Com. 36, 57, 59). The thrust of these suggestions was to limit the application of the proposal's monitoring requirements which applied to workplaces "where benzene is present" and the proposal's medical surveillance requirements which applied to "all employees who are or will be exposed to benzene." For the reasons stated below in the appropriate parts of this preamble relating to these requirements, OSHA has not adopted this suggestion.

A new definition of emergencies was added to the standard to clarify the type of situation requiring the use of a respirator. The definition of emergencies also clarifies the situations in which employees shall be provided with a biological screen.

PERMISSIBLE AIRBORNE EXPOSURE LEVEL. PARAGRAPH (c)(1)

Based upon a thorough review and evaluation of evidence in the record, OSHA has, as stated above, concluded that benzene:

(1) Is a human leukemogen;

(2) Causes bone marrow depression resulting in alterations in peripheral blood; and

(3) Causes chromosomal damage in blood cells.

These conclusions are based on studies ranging from single case reports to retrospective mortality studies and also experimental evidence. These studies represent the best available evidence upon which OSHA must make a decision. This decision is not predicated on any particular study, but is based on an assessment of the entire set of evidence taken as a whole.

OSHA recognizes that only recently has there been a well-designed study which may indicate a leukemogenic response among benzene-exposed animals. (Nelson, Ex. 178) In any event, the best evidence to date is that based on direct human experience. Based upon such evidence, OSHA concludes that benzene is and must be regulated as an occupational carcinogen.

Comment and testimony from industry for the most part, does not dispute the leukemogenic potential of benzene (e.g. Eckhardt, Ex. 115.B. 1, pg. 3; Tabershaw Tr. 2545). However, industry argues that this relationship is valid only at high exposure levels. In support of this view, they cite as evidence that: (a) the documented cases of benzene-induced leukemia were among employees who were, most probably, exposed to high concentrations, and (b) that several studies of undefined numbers of workers who may have been exposed to low levels of benzene did not demonstrate a leukemia excess (The benzene studies are described under Health Effects: Leukemia). Industry also believes that observable blood disorders precede the development of benzene-leukemia and that such hematological abnormalities are reversible (ORC, PC 34, p. 2; Tabershaw Tr. 2543 Jandl. PC 26B, Allied P.C. 22, p. 7). They conclude that the present exposure limits of 10 ppm TWA and 25 ppm ceiling are sufficiently protective to guard against the development of

non-malignant blood disorders and, consequently, that limiting exposure to such levels will also protect against leukemia. (ORC, PC 34; Jandl, PC 26B; Tabershaw, Tr. 2546.)

The issue of the levels at which cancer is induced by chemical agents and whether or not there is a "threshold" has been a major issue in every OSHA rulemaking concerning the regulation of occupational carcinogens (See preambles to Carcinogen standard (39 FR 3758); Vinyl Chloride (39 FR 35892); Coke Oven emissions (41 FR 46742). The benzene hearing was no exception. As in the case of arsenic, the lack of an unequivocal animal model (Kraybill, Tr. 758) requires that the Secretary's decision rely primarily on data obtained from human evidence. However, the epidemiologic method is by its very nature, a retrospective view of the evidence, i.e. findings of a recent excess of mortality among workers may relate to initial exposures occurring as much as 20 years or more previously and which most certainly correlate to exposures at higher concentrations than present levels. Because of these variables, it is extremely difficult to derive definite conclusions as to the quantitative health risk to the workers at exposures near 1 ppm. Studies which report negative findings, such as those studies conducted by Stallones, Tabershaw-Cooper and Thorpe suffer from the disadvantage of not being able to clearly define an exposure cohort, i.e., the identification of a group of workers actually exposed to benzene and to what levels they were, in fact, exposed. (Stallones, Ex. 115.C; Tabershaw-Cooper, Ex. 149A; Thorpe, Ex. 2-34). OSHA recognizes that it is extremely difficult to reconstruct and define employee exposures retrospectively. Therefore, given the uncertainty of the definition of exposure and the potential for dilution of mortality excess among those actually exposed to benzene and other methodological deficiencies, OSHA is reluctant to place substantial reliance upon these negative reports. Thus, there is little definitive information available pertaining to the leukemogenic risk of an adequate size cohort of workers exposed to benzene less than 10 ppm

and who have been followed for an adequate amount of time. Furthermore, it is OSHA's view following a careful review of the record that, at the present time, it is impossible to derive any conclusions regarding dose-response relationships for benzene (Goldstein, Ex. 75, p. 2 NRC, Ex. 2-4 p. 11) beyond the general observation that higher exposure levels carry a greater risk than do lower exposure levels. What is apparent however, is that a decrease in exposure level and/or duration will result in a decreased risk of leukemia.

OSHA also recognizes that, in some published cases with adequate documentation, leukemia attributable to benzene exposure developed after observable changes in the peripheral blood, i.e., various cytopenias, pancytopenia and/or aplastic anemia (Goldstein, Ex. 43B, p. 166). However, many cases of benzene-induced leukemias were recognized as such only after a patient with overt physical symptoms presented himself to a physician. Similarly, Snyder stated that, in the cases of pancytopenia and aplastic anemia, individuals "exposed to benzene usually do not approach their physicians until late stages in the disease" (Ex. 156.2, p. 2). As a result, the hematological picture before the onset of disease is often not known. Moreover, because of the well-known reserve proliferative capacity of the bone marrow it is possible that marrow damage may occur without being reflected in the peripheral blood (Goldstein, Ex. 43.B, p. 175; Wintrobe, Ex. 2-107, p. 676). Olson acknowledged that alterations in bone marrow activity can occur despite a normal blood count (TR. 2894). Moreover, Goldstein noted that some individuals may have significantly depressed blood values, and yet remain within normal ranges. For this reason, a pancytopenic response to hematotoxic agents may go unrecognized. Therefore, OSHA believes that the scientific evidence is insufficient for adoption of the hypothesis that a preceding prodromal blood syndrome is a necessary prerequisite for the development of benzene leukemia. In this

regard, Goldstein in his testimony cautioned that benzene may act as a direct-initiator of a neoplastic response.

OSHA is also aware that in many instances, non-malignant blood disorders resulting from chronic exposure to benzene may be reversed by removal from benzene exposure. However, the apparent high degree of reversibility, as set forth in Jandl's review, is open to question as pointed out in the Health Effects section.

Furthermore, a most characteristic finding which pervades the published literature, is that physiologic factors which cannot be identified a priori, such as nutritional state, genetic constitution, variations in metabolism of benzene and exposure (both occupational and non-occupational) to other marrow depressants, and the variables of age and sex may act to modify the individual's response. (Browning, Ex. 31, pp. 26 ff; Shaw, Tr. 421; Snyder, Ex. 156, p. 2.) For example, Browning stated, "* * * [t]here is no doubt that both men and women differ markedly in their response to similar conditions of exposure." (Ex. 31, p. 2.) Therefore, unqualified identification of high-risk subgroups cannot be made at present. Because of these uncertainties, this standard is designed to protect the most sensitive as well as the more resistant members of benzene-exposed worker populations by limiting exposure to the maximum extent feasible.

It is, therefore, clear from an examination of the record that a determination of a precise level of benzene exposure which presents no hazard cannot be made and that the corollary question of whether a "safe" level of exposure to benzene exists cannot be answered. The agency is aware of and has examined scientific opinion and data submitted by industry that thresholds for carcinogens may exist. However, prudent public health policy requires a conservative course of action until such evidence is of a definitive nature.

In its conclusionary document the International Workshop also stated: "[t]he workshop discussed but could not

agree on whether there was a concentration below which there would be no leukemogenic effect clearly attributable to benzene" (Ex. 17, p. 7). Kraybill testified that because there was not enough data at the lower part of the dose-effect curve, he was unable to estimate a "safe" level. As early as 1939, in presenting data on the effects of chronic benzene exposure including leukemia, Hunter stated: "It is doubtful whether any concentration of benzene greater than zero is safe over a long period of time." (Ex. 2-74, p. 354.) In 1974, the MAK-Werte Working Group stated, * * * [O]n the proven carcinogenic (leukaemogenic) effects of benzene and the lack of quantitative measuring data in the low concentration ranges, it is not possible at this time to establish an MAC (maximum allowable concentration) which might be regarded to be without danger." (Ex. 2-58, p. 52.)

Goldwater testified that zero is the level at which there is no risk of getting cancer from benzene (Goldwater Tr. 2500).

Goldstein stated: "As we do not know what the safe level is, the standard would appear to me to be based, must be based on prudent medical approach, which is to keep it at the lowest feasible level" (Tr. 352).

Aksoy stated: "[F]or me, the permissible exposure limit for benzene should be zero. Where it is technically impossible to achieve this, the permissible exposure limit should be lowest possible" (Tr. 149). In OSHA's view, the demonstration of cancer induction in humans at a particular level is not in the regulatory context, a prerequisite to a determination that a substance represents a cancer hazard for humans at that level. Relying upon a substantial body of scientific opinion, OSHA has concluded that, when dealing with a carcinogen, no safe level exists for any given population. For example, the National Cancer Institute's Ad Hoc committee on the Evaluation of Low Levels of Environmental Carcinogens (1970) states:

> no level exposure to a chemical carcinogen should be

> considered toxicologically insignificant for man. For carcinogenic agents, a "safe level for man cannot be established by application of our present knowledge" (Ex. 272, p. 1).

Thus, OSHA takes the position that in promulgating a health standard for a life threatening hazard such as benzene-induced leukemia, the exposure limits be established on a conservative basis so that worker health is properly safeguarded.

From the point of view of choosing a safe level of exposure, therefore, the permissible exposure limit should be set at zero. However, based on the evidence in the record, it is OSHA's judgment that a zero standard for exposure to benzene is not technologically feasible. In fact, it is clear that certain quantities of benzene are present in the ambient environment as a result of natural phenomena and as artifacts of human activity. While a permissible exposure limit equal to zero plus background would represent the lowest level theoretically possible, OSHA believes that the record shows such an approach is not feasible. Even if such a number could be determined, achieving a standard of zero plus background would require that exposure to benzene be effectively zero so as not to increase employee exposure above background levels. There has been no evidence presented that convinces OSHA that such a complete elimination of benzene in all industries can be achieved by existing or future technology. In determining the appropriate permissible level of employee exposure to benzene, OSHA relies in part on the record of this proceeding and in part on policy considerations which lead the Agency to conclude that, in dealing with a carcinogen or other toxic substance for which no safe level of exposure has been demonstrated, the permissible exposure limit must be set at the lowest level feasible. Such a determination involves a measure of subjective judgment which OSHA believes is justified by the nature of the hazard being dealt with, and the intent of the Act. Section 6(b)5 provides that the standards for toxic

substances shall be feasible. That section specifically provides that:

> In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws.

OSHA has determined that 1 ppm TWA, 5 ppm ceiling limit for 15 minutes is the level which most adequately assures, to the extent feasible, the protection of workers exposed to benzene. In making this determination, the Agency recognizes that many industries affected by this standard have already achieved this permissible exposure limit, in a good many of their operations. As shown below for worksites currently above these values, currently available engineering controls and/or modifications of work practices can effectively reduce employee exposure to below the 1 ppm TWA, 5 ppm ceiling. This might suggest that the lower permissible exposure limits could be established, if not for all, at least for some of the industries covered by the benzene standard. OSHA has considered the appropriateness of establishing lower permissible limits for those industry sectors which can achieve these lower limits. It is, however, difficult on the basis of the available evidence to make this determination. The benzene standard applies to a multiplicity of industries and exposures occur from such varying sources as leaks in closed systems to batch operations using solvents. Identification of some operations with lower exposure levels is possible in some industries, but even for these industries exposure information is not available for all operations. Moreover, even where information has been furnished by particular employers as to exposure levels for operations in their plants, it is not possible with any degree of confidence to apply this information to operations of another facility in the same industry. There is a great deal of variability in the configuration of plants, and

the physical location of operations within a plant varies from facility to facility. Finally, it is OSHA's view that different levels for different industries would result in serious administrative difficulties. Because of these widespread differences and diversity, OSHA has decided to apply to all affected industries a permissible exposure limit of 1 ppm. Several industrial situations have been examined in making this determination and are discussed below.

Oil and gas production work is conducted in outdoor open air environments with relatively low-benzene content (Tr. 1463) streams maintained in closed systems (Tr. 1463). Employee exposures in producing operations are intermittent and extremely low (PC 33API Brief p. 141; Ex. 116). Evidence in the record indicates employee exposures ranging between 0 ppm and 2 ppm, with over 80% of the measurements below 0.25 ppm (Tr. 1467; Ex. 116; Ex. 115.A.4, p. 8). Since the production of crude oil and natural gas occurs in completely enclosed systems, the only employee exposures result from leaking valves (P.C. No. 30) and, as already indicated, these exposures are minimal. Visual inspections can detect these malfunctions and correction can be accomplished largely through replacement of seals. Engineering controls in the form of "double sealed" or "canned" pumps could also be instituted to avoid the leaks.

Pipeline transportation of crude oil and refined products is primarily a closed system operation (Tr. 1460). Potential employee exposure may occur where the products are transferred by truck or rail (Tr. 1471). Other operations involving employee exposure are gauging, and sampling operations, all of which are of relatively short duration with minimal employee exposures (Tr. 1472). Measurements taken by industry indicate that most such exposures on an 8 hour TWA basis are below 0.5 ppm (Ex. 115, A.1). The only area in which exposures were shown to exceed the permissible exposure limit was in the additive handling operations in which benzene was being utilized as a diluent. Since benzene was not necessary to the process, it was being eliminated from that operation (Tr. 1473).

The unloading and loading of gasoline, crude oil, and other refined products from marine vessels results in limited exposure to shoreside personnel ranging between 0.01 ppm to 0.82 ppm with an 8 hour TWA of .2 ppm (Tr. 2271). The shoreside personnel's potential for exposure occurs during the connecting and disconnecting of the hoses and loading arms, an activity of limited duration (Fuller Ex. 115, A.3, p. 4). The unloading and loading of benzene from marine vessels, however, may result in higher employee exposures. The transportation by barge accounts for the majority of the total benzene transported (A.D. Little, Ex. 5A, 4.24, 4.42). The connecting and disconnecting, opening and closing of valves and the monitoring of fill levels are the typical operations in which employees will actively be involved. These operations are all of limited duration and, consequently, employees would spend little of their time involved in them. The remainder of the employees' time would be spent elsewhere removed from exposure. Therefore, work practice controls would be extremely effective in reducing employees' exposures to benzene during the unloading and loading of marine vessels (A. D. Little, Vol. 1, May 1977, p. 4.27).

One methodology discussed to reduce exposure to vapors is a marine vapor recovery system (Fuller, Ex. 115-A.3). However, at the present time questions concerning fire and explosion risk, and potential structural damage to barges have, not as yet, been adequately resolved.

The exposures measured during the unloading of gasoline at bulk terminals are low. Sexton, an industry spokesman, reported that the highest long-term samples on individual truck operators was 0.41 ppm, with the vast majority being below 0.2 ppm (Ex. 115-A.10). These terminals from which the exposure data was obtained represent examples of the

various types of truck loading techniques and different physical characteristics of the terminals, such as loading rates, covered versus uncovered loading racks, and floating roof tops.

Data presented by Williams Pipeline also showed exposure levels, for the most part, below 0.5 ppm on an 8 hour TWA basis. It, therefore, appears that one or a combination of these available engineering controls will be sufficient to reduce employee exposure below the permissible exposure limit.

Approximately 94% of the benzene produced is derived from petroleum through the process of catalytic reforming, recovery from pyrolysis of gasoline and hydroalkylation of toluene. Many of the processes used to produce benzene involve completely enclosed units such as reactors. However, these processes do contain vents and other sources of leaks, which can result in significant exposures (A. D. Little, Vol. II-B11).

Control of emissions can be accomplished by such activities as removal and reinstalling equipment such as pumps, compressors, machining of parts, cutting and welding of pipelines, fabrication of equipment, replacement of gaskets. Also, the use of automatic gauging devices, closed loop sampling sytsems, vapor recovery units, floating roof installations and rupture discs has been suggested (Ex. 5A, 4-53).

The majority of employees exposed at petrochemical plants are already within the permissible exposure limit (Ex. 111-A, pp. 4-7). At only four of twelve plants surveyed, exposures were above 1 ppm (ADL, May 1977, p. 10, Table 2), and of those four plants only two were above 5 ppm. The fact that eight of those twelve plants were already within the permissible exposure limit suggests that other plants can be rehabilitated with existing technology to achieve levels within 1 ppm.

The record indicated that exposures to benzene vary between 0.1 ppm and 20 ppm (Com. 28, 31). The differences in exposure levels appear to be due to the particular protective measures employed in the laboratory (Tr. 3157, 3492-6). On the basis of this evidence, OSHA has determined that the use of a properly operating laboratory hood is one available engineering control which is currently reducing employee exposures (see ADL 4-41) well below the permissible exposure limit. The type of control selected will be dependent upon the individual laboratory (ADL May 1977, pp. 4-40 and 4-41).

The two segments of the steel industry wherein benzene exposure occurs are the coke oven battery and the light oil distillation plants. Exposures at the coke oven batteries range between 0.02 ppm and 0.31 ppm (Ex. 135, p. 4 and Attachment 2). It is thus apparent that the steel industry's compliance with the Coke Oven Emission Standard will maintain benzene exposures well below the action level.

Within the distillation plants, equipment is used to distill the benzene out of the light oil. It is in this operation that the steel industries claim that in certain situations it will not be feasible to reduce exposures through engineering controls. It appears, however, that those situations are limited to the older "coke driven by-products plants" (between 30, 40, and 50 years old). (PC 36 AISI Brief, pp. 87-88) and does not exist for the newer plants which currently have low exposure levels.

As the Courts of Appeals have emphasized, OSHA is not restricted to the status quo. Standards may be set which require improvement in existing technologies or which require the development of new technology and OSHA is not limited to setting standards based solely on devices currently available, at least where new technology appears on the horizons to limit exposures below the permissible exposure limit. (See e.g. *Society of Plastic Industry* v. *U.S. Department of Labor,* 509 F.2d 301 (C.A. 2, 1975) cert. denied.)

Certainly here, the evidence indicates that technological controls to reduce exposures, if they are not universally used, do exist (Ex. 5A, 4-37).

Benzene exposure may occur in a variety of industries when solvents containing small quantities of benzene are utilized. Some examples are the rubber industry, the manufacture and use of adhesives, paint manufacturing and application, metal can production and commercial printing. Evidence in the record indicates that, with the exception of paint remover firms for the most part have restricted the use of benzene as a raw material. It appears, therefore that the percent of benzene coupled with presently available engineering controls, such as local exhaust systems, results in minimal employee exposures (May 1977, ADL p. 4-27, 4032).

Based on the record of the benzene rulemaking, OSHA has concluded, as indicated above, that the permanent benzene standard is technologically feasible. Furthermore, OSHA has determined that this standard better effectuates the purposes of the act than the national consensus standard for benzene.

Dermal and Eye Exposure Limits: Paragraph (c)(2). The final standard, like the emergency temporary standard and the proposed standard, prohibits all eye contact and skin contact with liquid benzene. This requirement is based on OSHA's policy that, in dealing with a carcinogen, all potential routes of exposure (i.e. inhalation, ingestion, and skin absorption) be limited to the extent feasible.

Although the record evidence does not conclusively establish what the effects of contact with benzene are on the eyes or the skin, participants generally did not oppose a requirement for restricting such contact. Indeed some participants indicated that they already provide protective clothing and equipment to their employees in order to protect them from possible hazards of contact with liquid benzene.

The record evidence on the effect of liquid benzene on the eyes or the skin is extremely limited. No scientific data as to the effects of benzene on the eyes was presented during the rulemaking proceeding. The few studies of skin effects on animals and humans (Ex. 2-46, 2-47, 2-48, Tr. 2459-90) are not definitive as to the extent of benzene that is absorbed through the intact skin or as to the comparative rate of absorption through damaged skin (Tr. 2469-70). Testimony as to skin absorption of benzene was given by NIOSH and by an industry expert witness. NIOSH's view is that benzene is readily absorbed through the skin although the extent of absorption in any particular exposure is unknown. NIOSH however, believes that in instances of an inflamed skin or when benzene is contained in a mixture a "considerable amount" can be absorbed (Tr. 860). Industry's witness stated that he had no personal view as to whether benzene is absorbed through the skin (Tr. 2469) nor whether the rate of absorption of benzene was or was not increased where the benzene is a component of a solvent (Tr. 2471-2). The witness also pointed out that he did not know the effect of multiple applications of benzene on the broken skin (Tr. 2471). He suggested that additional studies be conducted to resolve these issues. This witness nevertheless testified that liquid benzene can damage the outermost protective layer of the skin (Tr. 2470) and that, although there is no verifying data, "it is ordinarily assumed that penetration of any molecule will be greater through damaged skin that undamaged skin" (Tr. 2469).

In order to assure that employees are adequately protected against all benzene hazards, it is OSHA's belief that it is appropriate to provide precautions against eye and dermal contact with benzene. In reaching this conclusion, OSHA has taken note that the threshold limit value for benzene adopted by the ACGIH for 1976, and the intended change of that TLV, bear a "skin" notation which refers "to the potential contribution to the overall exposure by the

cutaneous route including mucous membranes and eye, either by airborne, or more particularly by direct contact with the substance. Vehicles can alter skin absorption. This attention-calling designation is intended to suggest appropriate measures for the prevention of cutaneous absorption so that the threshold limit is not invalidated" (TLVs for chemical substance in Workroom Environment with Intended Changes for 1976, p. 5). OSHA further notes that maximum allowable concentrations of benzene in other countries also carry a "skin" notation.

OSHA has reviewed the various suggestions for changes in some of the requirements of the provision on eye and dermal limits. Some participants suggested that the provision apply to "liquid benzene" to make clear that the limitation did not apply to eye and skin exposure to benzene vapors (For example, see Com. 53). OSHA has adopted this suggestion since it was never intended that the provision apply to other than liquid benzene. Some comments suggested that the limitation apply only to liquid benzene of a commercial grade or higher (Com. 48; Com. 76) so as to exclude solvents with trace amounts of benzene (Com. 59). There is no evidence, however, to suggest that the absorption rate depends on the amount of benzene present in the liquid (Tr. 2472, 2482).

Regulated Areas: paragraph (d). The final standard contains requirements for regulated areas. The purpose of establishing regulated areas is to limit the exposure at above 1 ppm to as few employees as possbile. The burden of the regulated area provision on the employer is expected to be minimal since the provisions require the employer merely to identify and control access to regulated areas and to notify the applicable OSHA area office of their existence and condition.

The standard requires that regulated areas be established where airborne exposures are above the permissible exposure limit and that access thereto be limited to authorized

persons. Regulated areas must be established at all worksites where the permissible exposure limit is exceeded. Although transportation was not specifically listed in the proposed regulated area paragraph, the regulated area requirements of the permanent standard apply to the transportation of benzene, as well as to workplaces where benzene is produced, reacted, released, packaged, stored, handled or used. The scope of the regulated area subparagraph is, therefore, identical to the scope of the standard. This identity of scope has the result that, while the loading of gasoline at the bulk terminals may require the designation of a regulated area, the transportation of the gasoline from the terminals does not, in as much as that transportation activity is exempted from the standard.

Some participants misunderstood the regulated area requirement in the proposal and thought that regulated areas must be established even where exposures are below the permissible exposure limits (Tr. 3136). The standard, however, requires establishment of regulated areas only where exposures are above 1 ppm as an 8 hour time weighted average or 5 ppm averaged over a 15 minute period.

Some participants recommended that regulated area requirements not apply to laboratories (Ex. 6, No. 37, 70) or to coke oven batteries (Ex. 135; p. 2 PH; 36 AISI Brief, p. 17). It is OSHA's view that existence of a hazard, rather than the type of operation, should be the basis for establishment of regulated areas. Therefore, if the exposures in laboratories or coke oven batteries were to exceed the permissible exposure limits, regulated areas would have to be established at those facilities. Moreover, OSHA feels that the burden is minimal compared to the protection afforded employees.

The standard requires that the OSHA area office be notified within 30 days following the establishment of a regulated area. Each employer must notify OSHA of the existence of any regulated areas within his establishment and

of the conditions existing within such areas. Since regulated areas are required to be established only where exposures to benzene exceed the permissible exposure level, employers whose operations are all below that level need not file the report. This requirement is designed for compliance purposes. One comment suggested that OSHA should require, as it did in the Emergency Temporary Standard on Benzene, notification of the use of benzene in every workplace where it is present (Com. 62). It is clear from the record evidence that benzene is present in some amount or other in a vast number of workplaces and that, consequently, a notification of use provision would be administratively burdensome to OSHA and employers without necessarily resulting in more effective enforcement of the standard. For this reason, the final standard, as the proposal, requires merely the notification of regulated areas. Other comments suggested that laboratories and other small users of benzene be exempted from this notification provision on the ground that their use of benzene is infrequent (Com. 70) and that the filing of this notice by "big users" would be sufficient to set priorities for facility inspections. OSHA does not agree. The amount of benzene used by research and testing laboratories will vary from time to time depending on the projects being worked on. Finally, the suggestion presupposes that facility inspections would be conducted solely on the basis of the frequency of use of benzene. However, even where the use of benzene is infrequent, impairment of employee health may occur particularly where the exposure is above the permissible exposure limit. Other industry comments requested that employers be relieved of notification of regulated areas where temporary regulatory areas of short duration are established for maintenance work or for special projects or when leaks in closed systems occur (Com. 46, 50). In view of the hazardous nature of benzene exposure, OSHA deems it essential to require notification of regulated areas in all cases where employees are exposed above the permissible exposure limit. Moreover, in a facility

where there are frequent leaks, the employer will be alerted by the necessity to report these leaks to the possible need to take additional measures to protect employees against such exposures. If the possibility exists that the permissible exposure limit will be exceeded from time to time, the maintenance of a regulated area at the location of the leaks will, of course, minimize exposure and minimize the reporting requirement. Some industry participants recommended that the standard include a method for "deregulating" the regulated areas once exposures fall below the permissible exposure limit (Com 45, Com. 53, Com. 57). OSHA does not feel that a formal method for deregulation is necessary. Since the standard does not require maintenance of a regulated area except where exposures are above the permissible exposure limit, the regulated area requirement does not apply where the employer has reduced the exposure levels below the permissible exposure limit. Nor would a deregulation procedure contribute to the protection of employees. Moreover, if formal deregulation were required, it would be necessary for the employer to file an additional notification with the OSHA area office should conditions change thereafter and the exposure again exceed the permissible exposure limits. In view of these considerations, a formal deregulation procedure would appear to be unnecessarily burdensome.

Monitoring: paragraph (e). Significant changes have been made in the monitoring section of the final standard in response to comments by participants. Briefly, the final standard requires all covered employers to make measurements to determine whether any employee may be exposed to airborne concentrations of benzene, and imposes different measuring requirements depending on whether exposure measurements are above or below certain levels.

The monitoring requirements are imposed pursuant to Section 6(b)(7) of the Act (29 U.S.C. § 655) which mandates that any standard promulgated under section 6(b)

shall, where appropriate, "provide for monitoring or measuring of employee exposure at such locations and intervals, and in such manner as may be necessary for the protection of employees." The purposes of monitoring are to determine the extent of exposure, to identify the source of exposure to the hazard and to enable the employer to select proper control methods and evaluate the effectiveness of the selected methods. Thus, monitoring enables employers to meet the legal obligation of the standard to assure that their employees are not exposed to benzene in excess of prescribed levels. Additionally, monitoring enables employers to notify the employees of their exposure level, as required by section 8(c)(3) of the Act, and provides information necessary to the examining physician.

The need to conduct exposure monitoring was generally accepted by participants in the rulemaking process (P.C. 35MCA brief, p. 55-b; P.C. 36; ORC brief, p. 7). Many comments, however, objected to the proposal's requirement to measure airborne exposures in all workplaces "where benzene is present" (P.C. 33; API brief, p. 127a; P.C. 34; ORC brief, pp. 7-8). Participants argued that the use of the term "present" is so broad as to encompass each and every employee at a facility (Ex. 6, No. 53). It was also argued that benzene is present in the ambient atmosphere (Ex. 6, No. 43; Ex. 84B, 18, Ex. 84A, p. 7) with the result that every work operation in every city would probably have to be monitored (Ex. 6, No. 43, p. 12). OSHA's objective is to minimize all occupational exposures to benzene. The term "presence" was used in the proposal to convey the intent that, whenever the exposure of any employee to benzene concentrations resulted from workplace operations at the place of employment, the employer was required to measure that exposure. OSHA does not intend that employees, who might be exposed solely from other sources, such as ambient levels of benzene, be covered by the monitoring requirements. In view of the confusion as to the meaning of the term "presence," the final standard does

not use that term but instead specifies the general classes of occupational activities which can result in employee exposure to benzene, and requires monitoring where any of these activities are conducted.

In conducting the monitoring of exposures, the standard does not require that each individual employee's exposure level be measured. Although individual measurement is the ultimate indicator of employee exposure, OSHA believes that a requirement for individual measurements may be too burdensome. Accordingly, the standard requires that the measurements be made by monitoring which is representative of each employee's exposure to benzene over an 8 hour period without regard to the use of respirators. It should be noted that the requirement for representative monitoring does not preclude an employer from taking individual exposure measurements of each of his employees; individual measurements are certainly considered to be representative; and the representative monitoring requirement is the minimum that the employer must meet.

In establishments having more than one work operation involving the use of benzene, the monitoring to be representative must be performed for each type of employee exposure within each operation. One participant requested that area sampling be permitted in order to lessen the burden and cost of monitoring each employee with a different job function (Ex. 6, No. 49, p. 4). Although the final standard does not specifically require personal sampling, monitoring under the standard must determine breathing zone exposures. Appendix B, IV, therefore, recommends that air sampling be taken in the employee's breathing zone. Area samples are generally not as direct a measure of employee exposure, and consequently, may not meet the requirement for representative monitoring, although where area sampling can be correlated with breathing zone exposures, area sampling may be used. OSHA, however, notes that while there are techniques to correlate area

sampling with breathing zone exposures, these are generally more burdensome than personal sampling and involve much more sophisticated data collection and analysis, including the performance of personal sampling to assure the correlation.

Some participants suggested that employers with several places of employment, in which there are workplaces with identical processes or operations, be permitted to monitor only a representative number of such locations (Ex. 6; Ex. 50, p. 3; Ex. 60, p. 7). The fact that work operations are in different geographical locations would not in itself preclude representative monitoring. However, it is the employer's responsibility to assure that identification of conditions, characteristics, activities, climate, etc. exist so that monitoring at particular sites would actually be representative of employee exposure at other sites.

The employer is also required to use a method of monitoring and measurement with an accuracy (at a confidence level of 95%) of not less than plus or minus 25% for concentrations of benzene of 1 ppm or more. Methods of measurement are presently available to detect benzene to this accuracy level (Tr. 342-3) and one such method is described in Appendix A, II, E. Industry participants expressed concern that consistent compliance with these accuracy requirements will be impossible (PC 36; AISI brief pp. 106-108). The record, however, indicates that, even where benzene is present with other organic solvents, the OSHA Analytical Method will still enable employers to measure low levels of benzene well within the accuracy requirement of the standard (Tr. p. 343). Indeed, it was suggested at the hearing that there is an alternate method for sampling, passive dosimeters, which may comply with the accuracy requirements contained in the proposal (Tr. 2381).

As earlier indicated, the standard requires all covered employers to initially measure the airborne exposure of all of their employees. Some participants objected to this requirement and recommended that initial monitoring be limited to those workplaces where there is a probability of exposure to benzene in excess of the permissible exposure limit (P.C. 36; AISI brief, pp. 73-74; P.C. 34; ORC brief, p. 8) or in excess of 10 ppm (MCA brief, p. 50). It is OSHA's view that a "probability" is too speculative where a carcinogen is involved, and that a more definitive basis is needed for determining employee exposure. It is, therefore, OSHA's decision to require initial monitoring at any level of exposure to a carcinogen. Initial measuring of exposure is necessary for the protection of employees particularly where, as here, the permissible exposure level is not a "safe" or "no effect" level but is predicated upon feasibility. Moreover, initial monitoring does not place an undue burden on the employer since he need not continue the monitoring for those employees whose exposures are below the action level.

The standard requires that the initial monitoring be conducted and the results thereof obtained within 30 days of the effective date of the standard. Several comments requested that a longer period, ranging between two months (Ex. 176) to six months (P.C. 36; AISI brief, p. 75; Tr. 3137), be allowed for employers to meet this requirement. OSHA has retained the thirty-day requirement. Since the final standard has a delayed effective date of thirty days after date of publication in the *Federal Register,* employers will have sixty days to comply with this requirement. OSHA feels that this period is sufficient to enable employers to secure sampling equipment, take samples, and obtain the results. Moreover, the standard permits employers, who have monitored within the last year, to utilize these measurements for purposes of compliance with the initial monitoring requirements, provided that the sampling and analytical method used meets the accuracy test of this standard and provided that the employer maintains a record of these measurements and notifies employees of their exposure levels. Employers who have already monitored

their employees' exposures within this period will, therefore, not have to conduct initial monitoring unless, because of a process, control or personnel change, they are required to redetermine exposures. In addition, to the extent that the initial monitoring requirement cannot be complied with because of the unavailability of professional or technical personnel or of materials or equipment, the temporary variance procedures of the section 6(b)(6)(A) of the Act may be appropriately utilized. As noted, however, it is not expected that this will be generally necessary.

The frequency of monitoring employee exposure has been modified in the final standard. The proposal would have required monthly monitoring where exposures were above the permissible exposure limit and quarterly monitoring of those employees whose exposure was below that level. The final standard does not require employers to repeat the monitoring where the initial measurements are below the action level, unless there is some change in operations which might alter the exposures. Where the exposure measurements are above the action level but not in excess of the permissible exposure limit, the employer is required to monitor quarterly. Where initial or subsequent monitoring indicates that exposures are above the permissible exposure limit, the employer must monitor monthly. In developing these requirements, OSHA has given serious consideration to the numerous suggested modifications of the proposal's requirements. These ranged from suggestions to lessen the frequency of repeated monitoring to suggestions that monitoring frequencies should depend on whether the process is stable or highly variable (Ex. 6, No. 40), or should be based on performance variables, such as frequency of use, quantity used (Ex. 6, No. 70) and engineering controls (Ex. 6, No. 12, No. 43), or should be at the discretion of a professional (Ex. 6, No. 43). Some participants objected to periodic monitoring where initial monitoring reveals exposures below the permissible exposure limit (P.C. 36; AISI brief, p. 76; Com. 36, 10, 37). OSHA agrees that

periodic monitoring is not necessary where exposures are shown to be below the action level. Accordingly, OSHA has eliminated the repeat monitoring requirement for operations below the action level. Where initial measurements are above the action level but do not exceed the permissible exposure limit, periodic monitoring is necessary to assure that exposures remain within that range and do not rise to above the permissible exposure limit. OSHA believes that quarterly monitoring is sufficient to detect substantial changes in exposures and to assure that employee exposures remain below the permissible exposure limit. Some participants objected to monthly monitoring where initial measurements are above the permissible exposure limits (P.C. 36; AISI brief, p. 76; Ex. 6, No. 50). Their rationale is that repeat monitoring serves no purpose since the hazard has already been identified (Ex. 170). They argued that the requirement to establish regulated areas where exposures are above the permissible exposure limit is a sufficient incentive for employers to remonitor a workplace as soon as they believe that the exposure has been reduced (P.C. 36; AISI brief, p. 76-7). As previously pointed out, monitoring serves other purposes than initial determination of employee exposure. Monitoring is a check on the efficiency of engineering controls: increased levels alert the employer to the need to check and possibly alter these controls. Increases in benzene levels may also necessitate changes in types of respirators. Exposure measurements remind employees and employers of the continued need to protect against hazards, and are also useful to the examining physician in determining whether the exposed employee is at an increased risk. OSHA, therefore, is of the view that repeated monitoring, where initial measurements are above the permissible exposure limit, is necessary to protect employees. Other participants expressed the view that this monitoring should be less frequent than monthly—that is, should be quarterly (P.C. 31; ORC brief, p. 9; L.C. 3); semi-annually (P.C. 36; AISI brief, p. 78; Ex. 6, No. 57), annually (Ex. 6, No. 59,

No. 76), or as frequently as significant changes are believed to have occurred (L.C. 19). In view of the leukemogenic hazard of exposure to benzene, it is OSHA's view that monthly monitoring, where exposures are above the permissible exposure limit, is necessary to protect the health of exposed employees.

The final standard also provides that employers may discontinue monitoring for those employees for whom two consecutive measurements taken seven days apart show exposures to be below the action level. Where employee exposure measurements fall below the permissible exposure limit but are at or above the action level, the employer may alter the monitoring schedule for those employees from monthly to quarterly after two consecutive measurements taken seven days apart indicate the reduction in levels.

The standard further requires that, whenever there has been a production, process, control, or personnel change which may result in new or additional employee exposure, or whenever the employer suspects that a change of employee exposure may occur, the employer must repeat the required monitoring. Redetermination of exposures in such instances is necessary so that the employer may take the necessary action to protect his employees, such as providing appropriate respiratory equipment, or instituting engineering controls. Redetermination is required only where there is a new exposure or an increase in exposure levels is suspected (Ex. 6, No. 76, No. 50). The required redetermination where there is a change of personnel was added to the final standard in view of evidence that exposure levels can change when different employees perform the work (Tr. 3093). This requirement does not mean, however, that the employer must remonitor every time there is a personnel change but he must redetermine exposures when the work practices of the substitute employee are such that an increase in exposure may result. Redetermination of exposure must also take place after the cleanup of spills and the

repair of leaks, ruptures or other breakdowns. One comment suggested that redetermination not be required in these instances (L.C. 19). OSHA has not adopted this suggestion. Spills, leaks, etc., can result in very high exposure levels (Tr. 1299; P.C. 30, p. 48), and the requirement to redetermine exposures after cleanup or repair provides one method of ascertaining that proper corrective methods have been instituted and employee exposures are not significantly altered.

The final standard further requires that employers notify each of their employees of the exposure measurement which represents that employee's exposure. This requirement is discussed in detail under Recordkeeping.

It should also be noted that paragraph (m) of the standard requires the employer to allow employees or their designated representatives an opportunity to observe the monitoring. The specific provisions of paragraph (m) are discussed below.

Methods of compliance: paragraph (f). The final standard, as the proposed standard, requires employers to institute engineering and work practice controls to reduce employee exposure to benzene to or below the permissible exposure limits, except to the extent that such controls are not feasible. This requirement is in accord with OSHA's policy that feasible engineering and work practice controls must be used as the primary methods of reducing employee exposures. This policy is based on the view that the most effective means of controlling employee exposures is to contain concentrations at their source through use of mechanical means combined with work practices rather than reliance on the variability of human behavior so critical to the successful use of respirators. Thus, the standard also provides that, in situations where feasible engineering controls and work practices are insufficient to reduce exposure to the permissible limits, the controls must nonetheless be used to reduce exposures to the lowest achievable level,

and then be supplemented by the use of respiratory protection.

In reaching the decision to require engineering and work practice controls as the primary methods of reducing benzene exposures, OSHA has carefully considered the objections of various participants. While recognizing that in many situations engineering and work practice controls are the preferred methods of reducing exposures to or below the permissible levels, several participants recommended that the hierarchy of control measures be eliminated and employers be allowed the freedom of selecting the control measure to be instituted (Tr. 3140). These participants particularly objected to the requirement that engineering controls and work practices be used to reduce exposure to the lowest achievable level even if that level is above the permissible exposure limit. Various arguments were made in support of this position. One participant pointed out that, where the controls will not reduce exposures sufficiently, respirators will have to be used anyway. This employer suggested that OSHA mandate the continued search for controls which are sufficient to reduce employee exposure, but allow employers to select any appropriate method of reducing exposures (Com. 43). As was pointed out in the benzene hearing (Ex. 59, p. 12), as well as in other OSHA rulemaking proceedings, respirators are the least satisfactory means of control because of difficulties inherent in their design and use. Respirators are capable of providing good protection only if they are properly selected for the types and concentrations of airborne concentrations present, properly fitted and refitted to the employee, worn by the employee, and replaced when they have ceased to provide protection. While it is theoretically possible for all of these conditions to be met, it is more often the case that they are not. Consequently, the protection of employees by respirators is not always effective and is, therefore, permitted only in certain specified circumstances. For example, proper facial fit, is essential but, due to variations in fit,

individual facial dimensions and the limited range of the facepiece configurations, such fit is difficult to achieve (Tr. 332-335). Often the work involved is strenuous and the increased breathing resistance of the respirator reduces their acceptability to employees. Safety problems presented by respirators must also be considered. Respirators limit vision. Speech is also limited. Voice transmission through a respirator can be difficult, annoying and fatiguing. Movement of the jaw in speaking also causes leakage. Communication may make the difference between a safe efficient operation, on the one hand, and confusion and panic, especially in difficult and dangerous jobs, on the other hand. Moreover, skin irritation can result from wearing a respirator in hot, humid conditions and such irritation can cause considerable distress and disrupt work schedules. It is clear, therefore, that respirators cannot be considered as the primary means of employee health protection. Nevertheless, respirators do provide some protection and OSHA has concluded that under certain limited circumstances, where no alternatives are available, respirators may be used to reduce employee exposures.

Industry participants further argued against a system of priorities because of alleged unfeasibility of engineering controls. Most of these participants' objections to methods of compliance, however, lie in the area of economic rather than technological feasibility (Com. 49, p. 5; Com. 54, p. 2; Com. 73, p. 3). As discussed below, OSHA has determined that this standard is feasible and that the implementation of engineering and work practice controls is for the most part technologically feasible. However, OSHA realizes that, under some particular circumstances, engineering and work practice controls may not be technologically feasible in a particular work operation. Therefore, the standard explicitly recognizes that an employer may demonstrate the infeasibility of engineering and work practice controls as to one or more operations in a particular process, and in these circumstances use respirators to provide the required

protection. The question of whether an employer has met its burden of establishing that engineering and work practice controls are infeasible in a particular work operation involves the consideration of many complex factors and a rational balance process. Factors such as levels of exposure, useful remaining life of the equipment and the effort made by the employer to implement such controls are relevant.

In addition to the obligation to institute engineering and work practice controls, except to the extent that such controls are not feasible, the final standard also requires that each employer establish and implement a plan, including schedules for reducing exposures to within the permissible exposure limit or to the greatest extent feasible, solely by engineering and work practice controls. These written plans must be furnished upon request for examination and copying to representatives of the Assistant Secretary and the Director. These plans must be reviewed and updated periodically to reflect the current status of exposure control. Some participants felt that the requirement for written plans was burdensome and unnecessary (Com. 45, 59). OSHA, however, views the requirement for written plans as an essential part of the compliance program since it will encourage employers to actually achieve the controls and also provide the necessary documentation to OSHA, employers and employees of the compliance methods chosen, the extent to which controls have been instituted and plans to institute further controls to achieve safe and healthful workplaces.

A compliance issue relating to the requirement for engineering controls and work practices in this final benzene standard involves the relationship of that requirement to the covered employers' legal obligation as to engineering controls under the prior benzene standard (29 CFR 1910.1000, Table Z-2). The new standard, at paragraph (f)(1), requires the implementation of engineering controls and work practices. OSHA views the two standards as a

continuum of enforceable obligations which have been crystallized in the standards promulgation. More specifically, in evaluating whether the employer has instituted controls, OSHA compliance personnel would consider not only the employer's performance under the new standard but also his prior obligation under its predecessor.

Respirator protection: paragraph (g). The final standard contains requirements for respiratory protection. The standard requires employers to provide and assure the use of respirators whenever the permissible exposure level is exceeded. Paragraph (g) makes clear, however, that respirators are only to be used when other means of control are not feasible, and that the use of respirators is not a substitute for engineering and work practice controls. The standard allows respirators to be used to achieve compliance with the permissible exposure levels only in certain specific situations. The reason for the limitations is that respirators are, as stated above, the least satisfactory means of exposure control.

The standard contains a respirator selection table to enable the employer to provide the type of respirator which affords the proper degree of protection. While the employer must select the appropriate respirator from the table for each work operation on the basis of the airborne concentrations of benzene, he may always select a respirator providing greater protection—that is, one prescribed for higher concentrations of benzene than present in his workplace. It should also be noted that OSHA does not anticipate, as previously suggested in the proposal, that a conflict between the respirator selection table of the benzene standard and that of the coke oven standard will arise. Industry data (Ex. 136, attach No. 2) indicates that benzene exposures at coke oven batteries are generally below 1 ppm and respiratory protection for benzene exposure will generally not be required.

The standard further requires that the employer select

respirators from among those approved by NIOSH under 30 CFR Part 11. Participants pointed out (Com. 41; Tr. 752; TR 139) that, although the standard's respiratory selection table permits the use of chemical cartridge respirators for concentrations of 50 ppm or less, NIOSH does not approve chemical cartridge respirators for benzene. OSHA is well aware of the fact that NIOSH does not approve organic vapor cartridge or canister respirators for substances, such as benzene, with poor warning qualities and that such respirators do not generally have end-of-service life indicators (Tr. 140). The standard's requirement for NIOSH approval, however, is designed to assure that only devices approved and certified by NIOSH for use against organic vapors be used, notwithstanding the fact that such certification carries a stated or implied prohibition against the use of these devices for substances with poor warning properties. The alternative would be to chance employee protection by allowing use of non-approved devices, or to require supplied air respirators or self-contained breathing devices which in many cases would give rise to extreme operational difficulties (Tr. 142). Since organic vapor cartridge and canister respirators currently approved by NIOSH have been shown to be effective in absorbing benzene vapors, neither of these alternatives is necessary.

To compensate for the lack of adequate warning properties of those respirators, the standard requires frequent replacement of the cartridge or canisters (Tr. 140). The standard requires that the cartridges or canisters be changed at the end of their service life or the end of the shift in which they are first used, whichever comes first. Some participants objected to the requirement to replace air purifying canisters and cartridges at the end of the shift. They felt that it would lead to waste (Com. 40), would do little to encourage research and development of an end of service life indicator (Com. 41), and would be too frequent where benzene concentrations are low and cartridge life is long

(Com. 65). Recommendations for longer periods varied (Com. 53; L.C. 3; L.C. 19; Com. 60). OSHA has considered these recommendations but has concluded that, in order to assure that employees receive the maximum protection from benzene vapors, cartridges or canisters must be changed at least at the end of each shift. Should NIOSH, at some later date, certify a benzene end of service life indicator, which demonstrates that the canister or cartridge is useful past the end of the shift, OSHA would allow the cartridge or canister to be used for the extended period. Accordingly, the final standard has been changed to make this clear and hence encourage research and development of an end of service life indicator for benzene.

The standard further requires that the employer institute a respiratory protection program in accordance with 29 CFR 1910.134. This section contains basic requirements for proper selection, use, cleaning and maintenance of respirators. The employer is also required to assure that the respirator is properly fitted and to allow employees to wash their faces and respirator face pieces. In addition, paragraph (j)(i) of the standard requires that employees be properly trained in the use of respirators.

The standard requires that the employer shall provide respirators and other clothing and equipment required for protection from exposure to benzene at no cost to the employee. OSHA has allocated the costs of respirators and clothing and equipment required for protection from benzene exposure to the employer in order to effectuate the purposes of the Act. The employers' costs in providing respirators and protective equipment and clothing were considered in the economic assessment. This language clarifies OSHA's position which has long been implicit in health standard proceedings under section 6(b) of the Act.

Protective Clothing and Equipment: paragraph (h). The final standard retains the requirement that, where the employee is exposed to eye contact or repeated skin contact

with benzene, the employer must provide and assure that employees wear the appropriate protective clothing and equipment. This requirement compels employers to furnish, where necessary, such items as goggles, face shields or gloves, or footwear.

The available scientific evidence on the intact and unbroken skin has been discussed above under Dermal and Eye Exposure Limits. Although the evidence on skin absorption of benzene is inconclusive, it is an "undisputed assumption" that the penetration of any benzene molecule will be greater through damaged skin (Tr. 2469-70). The record evidence also indicates that there are situations where employees are immersed or drenched with benzene liquids (Tr. 289, 292, 299). Liquid benzene on the skin may cause erythemia and blistering, and dry scaly dermatitis may develop on prolonged or repeated exposure (Ex. 2-3). Burns may occur from benzene spills (Tr. 292). One purpose of the protective clothing and equipment requirement is to protect employees from dermatitis and burns. Additionally, since benzene is a carcinogen and since breaks in skin surfaces commonly occur, OSHA has concluded that it is necessary to require personal protective clothing and equipment although the full effect of liquid benzene on the eye and the skin is as yet unknown. To do otherwise would be to leave employees unprotected and expose them to what might ultimately be shown as a most serious hazard.

Few comments were received on the protective clothing and equipment requirements. Some participants indicated that they already provide such protection to their employees (L.C. 4). One participant suggested that the extent of body exposure, which would trigger the need for the protective clothing, be delineated in the standard (Com. 55). OSHA, however, believes that the likelihood of eye or repeated skin contact and the resultant need for protective clothing must be assessed on the basis of individual workplace operations. One comment objected to the need for protective clothing

or equipment where 1 percent or less benzene is present in the liquid benzene. There is, however, nothing to indicate that such percentages would create a sufficiently reduced hazard to warrant total elimination of the requirement.

The final standard requires the use of "impermeable" protective clothing and equipment. This requirement was in the emergency temporary standard. The proposal, however, would have simply required "appropriate protective clothing and equipment." Where eye and skin protection are required, the protective clothing and equipment to be "appropriate" must not allow liquid benzene to reach the eyes or skin. To make this clear, OSHA has adopted the language of the emergency temporary standard. The impermeable clothing must prevent all penetration of benzene. Thus, where impermeable gloves are used, liquid benzene should not seep through the cuff or any other opening in the glove. This could very well increase the hazard to the employee. It appears, on the basis of testimony from the industry expert witness, that, when a chemical substance on the skin is covered with a totally inclusive material, the rate of permeability of the substance through the skin is greatly increased (TR 2464; 2473).

Hygiene Facilities

Although normally required in carcinogen standards (see Coke Oven and Cancer Policy), the final benzene standard does not contain any requirement for hygiene facilities, such as waste disposal, housekeeping, showers, change rooms, or laundering of clothing.

The question of what, if any, hygiene facilities should be included in the final standard was at issue in the benzene rulemaking proceeding. The most common view of participants in that proceeding was that hygiene facilities were not necessary because of the volatility of benzene (L.C. 19). Almost all participants felt that no hazard would be created by the absence of hygiene facilities. One witness, however,

testified that, in his opinion, the wife of a benzene exposed employee, who laundered her husband's work clothes daily died from benzene induced leukemia (Tr. 314). Unfortunately, no further information concerning this case was furnished. OSHA, consequently, finds that the record does not establish the need for a requirement for hygiene facilities.

Medical surveillance: paragraph (i). This standard requires that employers make available a medical surveillence program for those workers who are exposed to benzene at or above the action level of 0.5 ppm TWA. In addition, the regulation contains an emergency provision for the biological monitoring of employees exposed to a massive release of benzene.

Evidence contained in the record clearly indicates that a medical surveillence program is an appropriate measure. Hematologists, company physicians and other participants have recommended the inclusion of a medical surveillence provision in the final standard (Ex. 106; P.C. 30; Ex. 211; Ex. 17; Ex. 179, Bommarito, Tr. 3382). Also, a review of the record discloses that it is a current common practice of many industries to routinely examine their employees for evidence of benzene toxicity (e.g., Wodka, Tr. 1263; Com. 26; Joyner, Tr. 2286; Dow, Tr. 2967, 3021; Ex. 77H).

Section 6(b)(7) of the Act requires that employers make available medical examinations to ascertain whether the health of workers is adversely affected by exposure to toxic substances, where appropriate. The requirements contained in this regulation are designed to detect changes in the hematopoietic system resulting from chronic exposures to benzene which may be manifested in a range of blood disorders, including leukemia.

It is widely recognized that the major target organ in chronic benzene toxicity is the hematopoietic system, especially the bone marrow. This system has the attribute that

a sample of the peripheral blood offers a unique biological "window" on the functioning and health of this system, providing much direct visual information not readily available for other organs or systems.

It is OSHA's view that a medical surveillance program directed toward the early detection of hematopoietic dysfunction by examination of peripheral blood samples is an appropriate measure. This determination receives support from: (1) Studies showing that early blood dyscrasias have been detected in workforces screened by laboratory tests (and often in workers displaying no obvious physical symptomatology) (Greenburg, Ex. 2-8, p. 419; Savilahti, Ex. 2-95, p. 1; Goldstein, Ex. 43B, p. 138); and (2) that even in cases of acute myelogenous leukemia, a period of remission, unfortunately brief, may be effected in a substantial proportion of those afflicted with this fatal disease by appropriate treatment (ORC/Jandl, P.C. 34, p. 73-74). OSHA's decision is also supported by evidence that some cases of benzene-induced blood disorders may be reversed upon cessation of exposure and by appropriate treatment (ORC/Jandl, P.C. 34, p. 39).

The medical surveillance provision of the proposed standard was the object of much comment and testimony. For example, over 45 separate comments addressed this issue in prehearing submissions alone. Additionally, substantial testimony was adduced during the hearing, and additional views were submitted to OSHA in the form of post-hearing comments. These suggestions addressed both the content and frequency of the examinations as well as what information should be elicited from the medical/work history portion.

OSHA, in formulating the provisions of the medical surveillance section, was aware of several problems. While there is no disagreement that the blood tissues are the most important organ relative to chronic benzene toxicity, there are as yet no consistent patterns of abnormalities, espe-

cially at low exposure levels, and no specific pathognomonic tests of benzene toxicity (Rosen, P.C. 23A, p. 2). Compounding this problem is the fact that it is difficult to separate cases of early benzene hematoxicity from more common minor blood disorders (Goldstein, Tr. 354). Associated with the problems of exam content is one of testing frequency. There are simply no precise estimates of the time course of the various abnormalities to allow determination of optimal testing frequency. Opinions based upon the lifespan of the blood cells are equally inapplicable in determining the frequency of such exams (Battle, P.C. 26C). While realizing that the more frequent the exams the greater the probability of detecting blood disorders induced by benzene, OSHA is also aware of the practical considerations of a medical surveillance program. Unlike the coke oven standard which applies to a defined number of workers employed in well characterized work sites, benzene is a component (usually as a contaminant) of a wide variety of refined petroleum solvents and, therefore, some benzene exposure occurs in a myriad of work sites and work operations. OSHA also recognizes that to be effective a medical surveillance program must be acceptable to a majority of workers subjected to the examination, the tests must display a high degree of accuracy and reproducibility, and the program should be able to be performed in a routine manner without unduly taxing medical resources. Given the above facts, the prescribed medical surveillance program is designed to accommodate the purpose of detecting early blood disorders resulting from benzene exposure without being overly burdensome and unduly intrusive.

The medical surveillance program consists of three main elements: (1) An initial and periodic examination for all those employees exposed to airborne benzene concentrations at or above the action level, (2) evaluation of abnormal findings by a hematologist and, (3) a biological screen for workers who may have received excessive exposure as a result of an emergency.

Several commentators and hearing participants recommended to OSHA that the medical screening program should be, in some way, related to employee exposure, and several specifically suggested that an action level be utilized as the determining boundary (Com. 10; Com. 21; Com. 26; Com. 36; Com. 46; Com. 47; Com. 53; Com. 70; Com. 72; Com. 76; L.C. 3; PC 36; AISI brief). Many others felt that routine medical surveillance applied to all workers exposed to benzene without regard to degree of exposure, as was specified in the proposed standard, was an excessive requirement (e.g., Ex. 6-36). OSHA has examined these analyses and, as a result, has significantly altered the content of the surveillance program in the final standard. Furthermore, it is OSHA's view that the requirements of the medical surveillance program cannot be left to discretion of the examining physician because some physicians may not be fully aware of the wide range of effects resulting from benzene exposure.

The final standard requires that employers must make available an initial and periodic examination to any worker exposed at or above the action level. While it is the Agency's position that there is no "safe" level for benzene exposure, OSHA believes that the vast majority of workers exposed below the action level will not manifest blood dyscrasias, while those at or above this value are at greater risk, the precise extent of which is unknown. The inclusion of an action level concept will therefore limit medical surveillance requirements for those employees as to whom the probability of identifying benzene-induced blood disorders is in all likelihood minimal, and will focus such efforts on a population at increased risk.

Initial Examination

The initial examination has two components: a medical/work history and a series of laboratory blood tests. This differs from the proposed standard which drew no distinc-

tions between initial histories and examinations and subsequent ones. The final standard does, however, make such a distinction. The purpose of the history is to alert the physician to problems which may indicate an individual's increased sensitivity to benzene. The permanent standard requires the taking of a history with the data elements specified in the proposal.

Eli Lilly (Com. 38) and Dupont (Com. 46) generally agreed with the proposed history requirements, while Dow Chemical agreed with the intent, i.e., that a complete medical history with an emphasis on blood problems is an essential part of a benzene medical surveillance program. They felt, however, that the wording should be simplified so that the worker could supply the information him/herself with minimal professional assistance (Ex. 154). OSHA, recognizing the merits of this suggestion, has not chosen to mandate the precise wording of the history taken, but only to require that specific areas should be queried. The employer, therefore, has considerable latitude with respect to the actual format. Whether the employee answers the medical history or is questioned by a health professional is also left to the discretion of the employer. The standard does require, however, that all aspects of the medical surveillance program be under the supervision of a licensed physician.

One hematologist objected to the inclusion of questions pertaining to a family history of hematologic neoplasms, noting that there is little evidence associating these disorders with a predisposing increased sensitivity to benzene (ORC/Jandl P.C. 34, Add. 5, p. vii). Another hematologist also criticized this provision on the basis that the information obtained was both unreliable and of unknown relevance to benzene toxicity (P.C. 26C). Jandl also stated that genetically related hemoglobin alterations (hemoglobinopathies) are not highly relevant and are therefore of no predictive value (ORC/Jandl, P.C. 34). OSHA agrees that there is no known or even suspected association of benzene-induced blood dyscrasias with some hemoglobinopathies such as sickle cell anemia. However, Aksoy has reported findings that individuals with thalassemia (another hemoglobin disorder) may be more sensitive to the hematotoxic effects of benzene (Ex. 44). (It is not clear from Aksoy's testimony whether or not thalassemias are at greater risk of developing leukemias resulting from benzene exposure.) Moreover, he also observed a familial link with leukemia resulting from benzene exposure (Ex. 24). In view of Aksoy's findings, OSHA believes that it is appropriate that the questions in the medical history relating hemoglobinopathies and a family history of malignant blood diseases remain in the standard.

Battle recommended that the health history also include questions concerning possible exposure to marrow toxins, such as the use of insecticides and volatile cleaning agents in the home (P.C. 26C). Since exposure to these types of agents may have significant impact on the blood picture of examined workers, queries regarding exposure to other marrow toxins both in and outside of the work environment have been added to the history requirements.

The initial laboratory examination requires that a series of classical blood tests and also measurements of serum bilirubin and reticulocyte count be performed. As noted, there is no consistent pattern of blood abnormalities resulting from benzene exposure. Various investigations claim that the earliest sign of benzene hematotoxicity is anemia or leukopenia, or changes in red cell indices. Some believe that red cell enlargement (macrocytosis) (Goldstein, Ex. 75; Goldwater, Ex. 140) or an absolute lymphopenia (Goldstein) may be suggestive of early marrow damage. (Occasional observations of a paradoxical hypercellularity in response to benzene exposure have been reported, e.g., by Aksoy; however, the basic hematological workup should detect this particular response.)

An examination of the record demonstrates that there is

general agreement that the following laboratory hematological tests should be part of an initial or baseline examination:

(a) Red Cell count
(b) White Cell count
(c) Hematocrit
(d) Hemoglobin
(e) MCV—(mean corpuscular volume)
(f) MCH—(mean corpuscular hemoglobin)
(g) MCHC—(mean cell hemoglobin concentration)

These tests are routinely performed in most blood examinations; they provide basic information about all three blood cell lines. The normal values are well known, and the tests are usually automated with the attendant benefits of being highly reproducible and accurate.

Differential counts of white blood cells, also required by the standard, are not amenable to automation and are therefore performed manually under microscopic examination by trained technicians. Battle commented that white blood cell counts are no longer performed on a routine basis in his clinic and that such an assay is usually only performed in response to abnormal cell counts (P.C. 26C). However, other commentators have recommended the inclusion of a differential count as part of a basic hematologic examination (both the initial and interval tests) (ORC/Jandl, P.C. 34, pp. 46-51; Goldstein Ex. 75). In addition to providing information on the relative number of various white cell types, the differential count provides an opportunity to observe aberrant cellular morphology and to note any unusual proportions of immature cells. Jandl feels that scanning of the slide by a trained technician for these types of findings is of the utmost importance (ORC/Jandl, P.C. 34, p. 45). For the above reasons, a differential count is a required part of the laboratory examination. In addition to the basic laboratory tests, serum bilirubin and reticulocyte counts must also be done in the initial laboratory exam. These tests may provide information indicative of

hemolytic states and other abnormalities. Because of the non-specificity of these two assays relative to benzene toxicity, the time-consuming nature and instability of the reticulocyte preparations, these particular tests were the object of much comment and criticism. Several commentators stated that although these tests were of little value on a routine basis, they should be made part of a preplacement or baseline exam (Com. 28, 72). Based on a review of this issue, OSHA believes that these two particular blood examinations should be included as a part of the initial laboratory tests only, to provide a more comprehensive picture of a worker's hematological profile, for possible later comparative purposes.

Several hematologists stressed the importance of obtaining pre-exposure data as a baseline against which latter comparisons could be made (ORC/Jandl, P.C. 34, p. 36; Battle, P.C. 26C; Goldstein, Ex. 75, p. 5). The initial exam requirement of the standard applies to both employees already exposed to benzene at or above the action level as well as to new or reassigned employees who may be exposed at or above the action level. In the first case, the blood data obtained is not, of course, a true non-exposed baseline, but may be useful at a later date should significant changes in blood values occur. In addition, since the standard requires that an initial laboratory exam be performed for all new or reassigned employees prior to their actual exposure to benzene at or above the action level, pre-exposure baseline data will gradually become increasingly available in the years subsequent to promulgation of this standard.

As an aid to physicians for comparing the results of the most recent blood testing with early data, the recordkeeping paragraph requires that, at the completion of the differential count, the slide of a peripheral blood smear be made permanent and stored for possible future reference. Retention of the slide allows the examining physician to directly compare the most recent findings with earlier ones, especial-

ly with respect to possible changes in morphology of the blood cells; counting data alone would not permit this type of comparison.

Dow Chemical suggested that kidney and liver function tests should be performed as a part of the preplacement examination (Tr. 2967). OSHA recognizes that these laboratory examinations may identify conditions indicative of an impaired ability to detoxify benzene. However, given the low permissible exposure limit mandated by this standard, OSHA concluded that requirement of these tests would be excessively burdensome. In this regard, Goldstein testified that he saw no value to incorporate these tests (Tr. 380).

Periodic Examination

The medical surveillance section requires that a brief updated history be taken semianually at the time of one of the blood examinations. Battle suggested that such a history include queries as to exposure to drugs or chemicals as well as recent illnesses since the last history (P.C. 26C). Because these agents may act to adversely affect the hematopoietic system and may be reflected in the blood picture, OSHA agrees with these particular suggestions and has incorporated all of them into the requirements for the interval history.

The periodic laboratory tests are similar to those specified for the initial exam, except that serum bilirubin and reticulocyte assays are deleted since, as stated above, the two assays are required only in establishing a baseline. Comments received by OSHA concerning the frequency of interval blood examination ranged from quarterly (ORC, P.C. 34, p. 11; Tr. 3382, Tr. 270) to 3 times a year (Com. 28; Tr. 3328; Battle, P.C. 26C), semiannually (Tr. 3138) to those who felt the frequency should in some manner vary according to the exposure level (e.g., Tr. 2965, 6-10, 6-37, 6-47, 6-64, 6-76, 41-3, 41-19). Dow expressed the view that the frequency should be the decision of the responsible physician and related to the medical condition of the employee and the environmental control of the specific work area (Tr. 2965). As detailed previously, there is insufficient information in the record to allow a precise determination of optimum testing frequency. No completely reliable information exists on the number of months which elapse between the first laboratory signs of a blood disorder and the onset of clinical disease or what effect a particular time delay has on therapeutic outcome. There is no reason for casualness about the testing frequency though, since even if a blood change were to progress steadily downhill, early detection and treatment may provide substantial benefit. It is OSHA's judgment, following examination of the various options available, that a six month interval between routine blood examinations is appropriate.

The standard contains a provision, applicable to both the initial, periodic and emergency exams, requiring that employees' abnormal test results must be referred to a hematologist for further evaluation should certain specified warning signs appear. This provision, which was not a part of the proposal, is in response to recommendations that: (1) A hematologist be included in some manner in the medical surveillence program (ORC/Jandl, P.C. 34); (2) specific quantitative guidelines including ranges (Ex. 6-60) be given physicians; and (3) that additional laboratory tests should be given if an abnormal count becomes manifest or significant changes occur relative to baseline values (NPRA, Tr. 3325-3331; AISI, Tr. 3263-64; ARCO, P.C. 32C). With respect to item (1), an industry participant testified that it was already the practice at his company to refer workers to hematology specialists if blood abnormalities are discovered (Joyner, Tr. 2286-87), and Dow remarked that they discussed abnormal blood findings of workers with the hematologists (Tr. 3021). Also Arco commented that, if abnormal conditions arise among its employees exposed to benzene, follow-up examinations are given and medical treatment performed until blood tests reveal values within

the normal range (P.C. 32C). Also, Dow disclosed that, for its employee exposed to benzene, an increased medical surveillance program would result if conditions such as an undiagnosed anemia or leukocytosis were detected (Tr. 2984-85). Sakol has noted that ineffective and inappropriate medical treatment was given to workers apparently suffering hematological disorders from benzene exposure which ultimately evolved into a frank leukemia (Tr. 303). This incident further illustrates the need for a specialist's evaluation, if abnormalities are detected.

Again it should be emphasized that the question of what constitutes the earliest laboratory evidence of chronic benzene toxicity is not known with certainty (ORC/Battle, P.C. 26C, p. 3). It is known that the level of all 3 blood cell lines may be variously affected by exposure. However, examination of the benzene literature reveals that the hematological boundaries of what is considered "normal" have varied. More recent tabulation of normal *ranges* are those published by NIOSH (Ex. 2-2, p. 135) : Wintrobe (Ex. 2-107, p. 1791, 1794, 1795) and those submitted by Jandl (ORC/Jandl, P.C. 34, p. 29). The normal range of hematological values presented generally agree quite well, especially those given by Jandl and Wintrobe. It is OSHA's conclusion that laboratory findings beyond these ranges must require additional evaluation by a blood specialist. In specifying the values beyond which findings are considered abnormal, OSHA utilized the values in the above citations to yield the widest range (often the range limits do not exactly coincide) in order to minimize the burden on the employer in borderline cases.

However, as illustrated by Goldstein, it may be possible for some individuals to experience a significant hematological response to benzene exposure and yet exhibit blood values within the range normal for the population as a whole (Goldstein, Tr. 356). To identify such workers for referral to a hematologist, the standard also includes as a

trigger, an allowable deviation figure for certain indices, relative to an earlier determined value. The advantage of this approach is that the individual acts as his own control. As early as 1926, Greenberg in recommending criteria for exclusion of workers from further benzene exposure, utilized as one of his criteria changes in the blood picture based on results from previous examination of individual employees. He recommended a determined value of a 25% decline in red and white cell levels. The red cell count, hemoglobin and platelet count are generally very stable indices and usually do not vary in individual cases by more than $\pm 10\%$ from baseline values. OSHA believes that a deviation of $\pm 15\%$ or more in these indices compared to the laboratory findings obtained in the most recent test is of sufficient concern to require the attention of a specialist. As white cell counts commonly exhibit greater variation, a percentage deviation trigger would be too restrictive and is therefore not included in the standard. In lieu of a percentage deviation, limits of normal ranges are prescribed.

Emergency Situations

The emergency medical surveillance provisions reflect OSHA's concern for those employees normally subject to low average exposures but who, because of equipment breakdown or other causes, may be exposed to massive doses of benzene. These workers may be at a relatively high risk for developing adverse hematological effects.

If a worker is exposed to a massive release of benzene, the employer must provide for each individual so exposed a urinary phenol assay at the end of the work shift in which the emergency occurred. If the results of such a test corrected to a specific gravity of 1.024 are less than 75 mg/l, no further testing is required. However, if a urinary phenol result is greater than 75 mg/l, indicating an average exposure above 10 ppm (Watts, Ex. 2-109), then a complete blood count including a differential count must be performed as soon as practicable.

If the red blood cell or platelet count or hemoglobin differ more than ± 15% from the most recent prior exam's findings, the worker's test results shall be referred to a hematologist for additional evaluation. Also, if the levels of the three formed elements lie outside of the prescribed ranges further evaluation by a hematologist shall be required.

The use of a urinary phenol assay to determine whether additional tests are indicated for workers exposed to high concentrations of benzene is supported by evidence in the record. The Sun Oil Company reported that special urinary phenol screening tests are prescribed for all persons when 10 ppm exposure levels are suspected (Ex. 77F).

For all types of medical examinations, the employer is required to provide the physician with certain information. This information includes a copy of the regulation, a description of the affected employee's duties as they relate to the employee's exposure, the results of the employee's exposure measurement, if any, or the employee's anticipated or estimated exposure level, a description of any personal protective equipment used or to be used, and information from previous medical examinations of the affected employee to the extent that it is not readily available to the physician. The purpose in making this information available to the physician is to aid in the evaluation of the employee's fitness to work in areas in which the exposure is at or greater than the action level. It should be noted that the standard does not require that a copy of the regulation be given to the physician for each employee. One copy would be sufficient, provided the employer informs the physician which employees are covered by this standard. Information that relates to individual employees or categories of employees (such as the description of job duties) need be transmitted to the physician only once, unless, for example, the duties change. Exposure measurements will be cumulative so that the results of each monitoring since the last examination are to be sent to the physician. However, since sampling may be done on a representative basis, the language of the standard requires the physician to be given either the employee's actual exposure measurements, if available, or the estimated level.

Several criticisms and suggested changes, discussed below, were also received by OSHA in regard to paragraph (i)(6) of the proposed medical surveillance requirements. In the final standard, the employer is required to obtain a written opinion from the examining physician containing: the physician's opinion as to whether the employee has any detected medical conditions which would place the employee at an increased risk of material impairment of health from exposure to benzene, the results of the medical tests performed, and any recommended limitations upon the employee's exposure to benzene and upon the use of protective clothing and equipment such as respirators. This written opinion must not reveal specific findings or diagnoses unrelated to occupational exposure, and a copy of the opinion must be provided to the affected employee.

Dow Chemical expressed the opinion that the notification requirements were overly burdensome and that the physician should be required to notify the employer and the employee only for the following reasons: Evidence of benzene toxicity, recommended limitations on worker exposure to benzene for any reason, or a health condition that precludes the use of protective clothing and equipment (Tr. 2966). The Rubber Manufacturer's Association offered the comment that the physician's written opinion should be supplied to the employee only if requested (Ex. 6-59, p. 5). One commentator cautioned that because of malpractice considerations, a physician might be reluctant to sign such an opinion (National Paint and Coatings Association, Inc. (NPCA, Ex. 41-14, p. 15). Also because of malpractice considerations, the American Iron and Steel Institute recommended that this section be deleted (P.C. 36, p. 109). ORC suggested language changes for this physician's opinion

requirement (ORC, P.C. 34, p. 11, Ex. 6-76, p. 11). The NPCA also warned that unless the physician's opinion paragraph was altered, denial of clearance for many prospective employees may result (Ex. 41-14, p. 15). There was also comment concerning with whom the doctor's opinion should be shared. ORC felt that any medical findings or diagnoses should be kept strictly confidential between the worker and the examining physician (P.C. 34, p. 11; Com. 76). Finally, a suggestion was received from industry that paragraph (i)(6)(ii) which limits the physician's opinion to specific findings and diagnoses related only to occupational exposure should be deleted on the basis that the employer has a right to know if there are any reasons related to work or not, that might have an adverse effect upon an employee or may possibly jeopardize fellow workers (American Coke and Coal Chemicals Institute, Ex. 176, p. 9).

The purpose in requiring that specific findings or diagnoses unrelated to occupational exposure not be included in the written opinion is to encourage employees to submit to medical examination by removing the fear that employers may find out information about their physical condition that has no relation to occupational exposures.

The purpose in requiring the examining physician to supply a written opinion containing the above mentioned analyses is to provide the employer with a medical basis to aid in the determination of initial placement and to provide information on a continuing basis concerning whether or not the worker is at increased risk as a result of his/her benzene exposure. Requiring that the opinion be in written form will serve as an objective check that the employers have actually had the benefit of the information in making these determinations. Likewise, the requirement that the employee be provided with a copy of the physician's written opinion will assure that the employee is informed of the result of the medical exam and may take appropriate action.

Comments suggesting that the physician's opinion be communicated only if there are problems or only upon request are not acceptable to OSHA on the basis that the employer has the ultimate responsibility to assure the protection of the worker's health. Where the findings are negative, transmittal of the doctor's opinion also provides necessary information to both parties that the employee's health has not been adversely affected and provides documentary evidence that the prescribed tests were performed and were evaluated.

Other aspects of paragraph (i) of the medical surveillance section are to be discussed under Recordkeeping, paragraph (1).

Mandatory Removal and Rate Retention

Among the issues in the benzene rulemaking were whether OSHA should include a mandatory removal requirement—that is, a provision prohibiting the exposure of an employee to benzene if the employee would be placed at increased risk of material impairment to health because of such exposure, and whether OSHA should include a rate retention provision—that is, a provision requiring the transfer of such employee to another job or providing that removal for medical reasons should not result in loss of earnings or seniority status to the affected employee. These issues, as OSHA has previously stated (41 FR 46780), are related and must be addressed together. Both employee and industry participants expressed their views as to several aspects of these issues in prehearing comments, in testimony during the hearing and in post hearing arguments. Subsequent to the close of the record in this proceeding, however, OSHA conducted an informal public hearing on mandatory removal and rate retention for workers exposed to lead as part of the rulemaking proceeding on lead. Consideration of the critical issue of medical removal protection is being undertaken for several pending standards together. Once this

consideration is completed, OSHA will consider the extent to which the conclusion on medical removal protection are appropriate for benzene and will propose the inclusion of those provisions in the benzene standard. The final standard published today, therefore, does not address the issues of mandatory removal and medical removal protection.

Employee Information and Training: paragraph (j). The standard requires each employer to provide training to each of his employees who is or may be exposed to benzene. The need to train employees was not disputed by participants in the rulemaking proceeding. Some comments, however, suggested limiting the training to certain employees. One industry comment requested that workers in closed system operations be excluded from training (Com. 47). Testimony at the hearing, however, revealed that leakages in closed systems are not unusual occurrences and that employee exposure during leaks can reach high levels. One comment suggested the exclusion of workers in open system operations where the benzene content is 1 percent or less (Com. 47). However, as stated above, it has been established that a consistent predictable relationship between the amount of benzene in a mixture and exposure levels does not exist and this suggestion has, therefore, been rejected. Another comment suggested the exclusion of laboratory personnel from training requirements on the ground that laboratory personnel have a good understanding of the hazardous nature of benzene (Com. 70). A laboratory technician, however, testified that during his six years working with many toxic chemicals, including benzene, he received no training (Tr. 3493) and indeed neither he nor his coworkers were aware of the fact that there was an OSHA standard limiting exposure to benzene (Tr. 3492). Information and training are essential for the protection of an employee. Each employee can do much to protect himself if he is fully informed of the hazards in his workplace and the protective equipment he should use. Furthermore, each employee, who is fully informed of the obligations which

the standard imposes upon the employer, can determine if he is working in a safe and healthful environment. For the reasons stated herein, OSHA believes that training must be provided to all employees in workplaces where benzene is present.

A trade association, while not disputing the need for training, suggested that employee training not be included in the benzene standard but await development of a comprehensive employee information and training standard based on the report of the Advisory Committee on Hazardous Materials Labeling and/or NIOSH's criteria document entitled "A Recommended Standard * * *.

An Identification System for Occupationally Hazardous Materials" (L.C. 14). OSHA deems it necessary for the protection of the health of employees to include the training requirements in the benzene standard at this time.

The standard specifies the contents of the training program. The information which must be imparted to the employee must include the nature of benzene related health problems, the necessity for exposure control, and the purposes of medical surveillance and respiratory protections. No participants objected to any of these items. Two participants suggested that employees should also be trained in "early symptom diagnosis to detect acute leukemia" (Ex. Dow Venable statement, p. 3; Tr. 3192; Ex. 154; Tr. 2963-3056). These participants, however, testified that the most common manifestations of acute leukemia are fatigue and nosebleeds and that these symptoms are not specific to acute leukemia (Tr. 3193).

The signs and symptoms of benzene-induced diseases are described in considerable detail in Appendix A and Appendix C. Both the proposed standard and the final standard specifically require that the employees be informed, among other things, of the information contained in Appendix A and Appendix C. (In this connection, the employee should

be instructed to report promptly the development of any of these symptoms which could be attributed to benzene exposure.) In view of the requirement to include the information contained in the appendices as part of the training program, an additional requirement on early symptom diagnosis would be redundant. Similarly, since Appendix B details the volatility of benzene, OSHA has not adopted NIOSH's suggestion (Baier statement, Ex. 84A, p. 11) that the standard further emphasize training on the flammability of benzene.

In addition to informing employees, the standard requires that the employer make available to his employees a copy of the standard and its appendices. This requirement is intended to assure that employees understand their rights and duties under the standard.

A public participant suggested that employers be required to hold classes for the training of each employee (Ex. 183, p. 5). OSHA has not included any specific requirement to this effect in the final standard, preferring to leave the manner of training up to the individual employers. Some employers will need to train individuals on a one-to-one basis, depending on the number of employees at a particular workplace or involved in particular operations. Employers with a few employees may find it burdensome or disruptive of work schedules to conduct training in class sessions.

The employer is also required to provide, upon request, all materials related to the training program to the Secretary and the Director. This requirement is intended to provide an objective check of compliance with the content requirements of the training program.

The standard requires that training of employees be conducted within ninety days of the effective date. Newly assigned employees must be trained at the time of initial assignment. The standard further requires that training be

repeated annually. These requirements were not explicitly in the proposed standard; however, they are consistent with OSHA's policy on training (see, Coke Ovens Emissions Standard) and have been included in the final standard to assure that employees are trained promptly and receive continuing education essential to the protection of their health.

Signs and Labels: paragraph (k). The requirements of the standard regarding the posting of warning signs and affixing caution labels remain primarily the same as those in the proposal with some difference in the legend of these signs and labels. These requirements are consistent with section 6(b)(7) of the Act which prescribes the use of labels or other appropriate forms of warning to apprise employees of the hazards to which they are exposed.

Signs. The standard requires the posting of warning signs in regulated areas. Some industry comments objected to this requirement on the ground that the training requirements of the standard are sufficient for informing employees of the hazards of benzene (Com. 28). In light of the serious nature of the hazard of exposure to benzene, OSHA does not agree. Not every employee will have completed his training before entering an area of operation where the exposure to benzene is over the permissible exposure level. Moreover, even trained employees will need to be reminded of the locations and the dangers of entering these areas. Additionally, other workers, such as employees of independent maintenance contractors who are authorized to enter particular regulated areas, need to be warned of the hazard and reminded to use protective equipment. OSHA, therefore, believes that both signs and training are necessary to adequately apprise employees of the hazards of benzene.

Other comments requested that laboratories be exempted from the sign requirements (Com. 70) on the ground that laboratory personnel are familiar with the hazards (Com.

20) and because there are already too many other hazardous substances in these workplaces (Com. 28) for which signs are posted (Com. 37). One comment expressed the view that there is no hazard from exposure to benzene in laboratories or other physical areas where the content of benzene in the mixture used is small (Com. 63, 59) or where benzene is used infrequently (Com. 70). As stated above, there is no established consistent predictable relationship between the amount of benzene and the exposure level, nor does infrequency of use eliminate the hazard. Signs are required by the standard only in regulated areas where, by definition, the exposure is above the permissible exposure limit. Furthermore, as stated above, OSHA believes that training in hazards alone is not sufficient to inform employees of the potential health hazards of entering or working in a regulated area and the need for the use of protective equipment.

Since warning the employees is necessary, the standard explicitly provides that the employer must assure that nothing which detracts from the required information appears near or on the sign. Laboratory and other employers who have other signs posted in the regulated area, therefore, have the responsibility for meeting this requirement.

Another comment pointed out that signs would be required even where benzene was in a closed system regardless of lack of employee exposure (Com. 65). This comment appears to overlook the fact that signs would be required only in those areas where employee exposure is over the permissible exposure limit and that, if there is no benzene exposure from the closed system, no sign is required. This same comment suggested that signs would be required where benzene was in a sealed container. Since there is no exposure to employees when benzene is in sealed containers, the standard exempts sealed intact containers from all requirements but the labelling and training requirements; hence signs would not be required in areas where benzene is present solely in sealed intact containers. Another comment suggested elimination of sign posting requirements for gasoline products (Com. 55). Since benzene is present in gasoline there is, of course, a benzene hazard attendant to exposure to gasoline. However, sampling data indicates that exposure to benzene is usually below 1 ppm, which would, in such cases, obviate the need for signs.

The standard specifies the wording of the signs. The purpose of this provision is to assure that the proper warning is given to employees. Some participants suggested that the word "Cancer" be replaced by "Leukemia Suspect Agent" (AISI, Princ. Wit, Ex. 156. Tab. I, p. 34; P.C. 36; AISI brief, p. 108; P.C. 35; MCA brief, pp. 103-5, Com. 39). In view of the fact that it has been established that benzene actually induces leukemia, OSHA does not agree that "Leukemia Suspect Agent" adequately informs employees of the hazard. For the same reason, OSHA has not adopted the suggestion of another comment that the sign merely warn of the presence of breathing zone vapors which "may" be hazardous, the need to wear respirators and that unauthorized persons should stay out (Com. 69). One comment pointed out that the sign requirements do not warn of other serious health hazards that may result from exposure to benzene. Addition of the various other health hazards would increase the wording on the sign with the likely result of detracting from the cancer warning. The reference to the most serious hazard is, in OSHA's view, a sufficient alert to employees that entering the regulated area may be hazardous. Some comments objected to the use of the term "Cancer Hazard" (Com. 26) on the ground that it would only serve to unduly alarm employees (Com. 28, 50). One comment suggested "Cancer Suspect Agent" be used to conform with 29 CFR 1910.1017 which regulates occupational exposures to vinyl chloride. Since exposure to benzene creates an increased risk of leukemia, and since leukemia is cancer of the blood, OSHA does not believe that the hazard is overstated by the use of the term "Cancer Hazard." Nor has OSHA adopted the suggestion that the word "Leu-

kemia'' replace the word ''Cancer'' (Com. 76). While the term ''Leukemia' is more specific of the nature of the hazard, ''Cancer'' is the more familiar term and thus more readily alerts the employee.

Another comment (Com. 69) suggested that the word ''Caution'' be substituted for ''Danger'' to conform to 29 CFR 1910.145(c)(1) and (2) which provide that danger signs should be used only where an immediate hazard exists, and caution signs used only to warn against potential hazards or to caution against unsafe practices. The suggestion was based on the view that OSHA failed to show that there exists a cause-effect relationship between employee exposure to benzene concentrations below 10 ppm. In view of the epidemiological evidence of the human carcinogenicity of benzene, OSHA feels that the use of the word ''Danger'' is appropriate. Furthermore, the word ''Danger'' is used to attract the attention of workers, to alert workers to the fact that they are in a hazardous area, i.e., an area where the permissible exposure limit is exceeded, and to emphasize the importance of the message to follow. The use of the word danger is consistent with the Coke Ovens Emissions Standard and other recent health standards.

Two comments objected to the legend ''Respirator Required'' pointing out that respirators are not always required in regulated areas. The reason given was that, although the concentration within a regulated area will be above 1 ppm, the employee would not have to use a respirator if his 8-hour TWA were below 1 ppm and his 15 minute ceiling is below 5ppm (Com. 46, 59). OSHA recognizes that some employees entering regulated areas may not be exposed above the permissible exposure limit. It is likely, however, that there will be many employees who work in the regulated areas for such periods of time or at such levels of exposure that they would without respirators be exposed to well above the permissible exposure limit. For this latter group, respirators would be required to reduce their exposure levels. To assure that these employees are adequately protected, it is necessary that the sign alert them to the need to wear respirators. Moreover, since even persons who are in a regulated area occasionally and are not exposed over the permissible exposure limits may face an increased risk of leukemia, OSHA does not believe that the respirator warning is such an overstatement as to necessitate elimination of that warning from the sign.

One comment pointed out that the warning sign ignores the flammability of benzene (Com. 50). NIOSH also recommended that the potential danger for fire be displayed on signs with equal prominence with the toxicological hazards. (Tr. 755) OSHA agrees. Benzene, as has been stated, is a highly flammable liquid. Accordingly, in the final standard, OSHA has added a requirement that the signs also contain the legend ''Flammable—No Smoking'' with equal prominence to the legend ''Cancer Hazard.''

Labels. The standard requires the use of caution labels on all containers of products containing any amount of benzene. This requirement imposes upon the employer the obligation to assure that all such containers within his workplace are at all times properly labeled. Some industry comments requested that OSHA define ''container'' (Com. 46, 55, 65) in terms of sizes and types of containers (Com. 53; Com. 72). Participants also appeared to be confused as to whether storage tanks, pipelines, tank cars and tank trucks are such containers as would be require labeling (Com. 60). The purpose of the labeling requirement is to assure that, wherever benzene is present in any quantity, employees are apprised of the hazard. The size or type of the container or its use as a storage vessel is, therefore, not material to this objective. In imposing the labeling requirement, however, OSHA does not intend to include pipelines, or to include trucks or other vessels transporting benzene products in sealed containers. At many points of pipelines, there is no employee exposure nor can the point at which benzene

enters a product stream often be determined. Benzene in liquid mixtures, other than in gasoline, is often transported in closed containers, in which case labeling of the container is sufficient without a need for labeling the transport vehicle. Where benzene products not in containers are transported in barges or other tank vessels, such as tankers and tank trucks, it is, of course, necessary that the vessel be labeled. With regard to gasoline, the standard does not cover activities past the bulk terminal and, therefore, gasoline trucks would not require labelling. In view of the above, the standard specifically excludes from the labeling requirements pipelines and any transport vessels or vehicles where the benzene product is transported in sealed containers.

Some participants suggested that the labeling requirements apply only to containers which have liquids with greater than 1% benzene (Com. 53, 72). It was also suggested that labels be affixed only to containers from which exposure to benzene levels above the permissible exposure limit might be reasonably expected to occur so as to exclude a requirement to label finished products which might contain trace amounts of benzene (Com. 59). Since there is no known safe level of exposure to benzene, OSHA feels that, for employees to be adequately apprised of the hazard, all containers must be labeled in the same manner.

The standard requires that the caution labels remain affixed when benzene products leave the employer's workplace. Some comments questioned OSHA's jurisdiction to impose such a requirement (Com. 50, 55, 59). The purpose of this requirement is to assure that all employees, not only those of a particular employer, are apprised of the hazardous nature of benzene exposure. It is OSHA's view that informing employees of the hazards to which they are exposed is an important element in reducing occupational disease and injury and one of the significant purposes of the Occupational Safety and Health Act. Section 6(b)(7) of the Act, which explicitly provides for regulation requiring

the use of labels or other appropriate forms of warning to apprise employees of the hazards to which they are exposed, is broadly drawn. This section does not limit the employer's obligation of informing employees of hazardous conditions to the employer's own employees. When an employer manufactures, formulates or sells a product containing a toxic substance, that employer is exposing not only his own employees but also the employees of other employers involved in handling, transporting or using the product. The extent of the obligation to inform should be commensurate with the extent of the exposure. This is especially true where the manufacturer, formulator or seller will in many cases be the only employer capable, through his unique knowledge, of providing the information needed for protection of employees. A narrower reading of the statutory authority would defeat the protective purposes of the Act by withholding from employees down the line who come into any contact with the product, adequate information as to the hazard. Furthermore, the use of the labels will alert other employers, who utilize or handle the product and who would not otherwise know of the presence of benzene in their workplace, of their obligation to comply with the standard. OSHA, therefore, feels that this requirement is necessary and appropriate to effectuate the purposes of the Act.

The standard prescribes the legend that must be included on the label. This is to assure that employees are alerted to the fact that they are handling benzene and to the hazard involved. The record evidence establishes that a variety of code names have been used for benzene (Ex 61, Sakol) and that employers (Tr. 3383; 3516), workers (Tr. 3402) and physicians (Tr. 305-6) often do not know that the product contains benzene. Some participants suggested that labels state the percentage of benzene in the product (Com. 58, 21, 59). In order to keep the label information to a minimum and since there is no consistent predictable relationship between the amount of benzene in the product and the per-

centage level, the final standard does not require any such statement on the label.

Recordkeeping and reporting. The provisions for recordkeeping, reporting, availability of records and the transfer of records are similar to those in the proposal. Such changes as have been made in the final standard are in response to the request of public participants that OSHA reduce the burden imposed by these types of requirements. These provisions implement the requirements of section 8(c)(1) and (3) of the Act, and are consistent with OSHA's general policy concerning records and reports.

Records: paragraph (1). The standard requires a limited amount of recordkeeping. Employers must maintain exposure measurement records and medical records.

The need for keeping these records was generally accepted by the participants in the benzene rulemaking. The common purposes of these recordkeeping requirements is to assure the employer's compliance with the control measures designed for the protection of his employees, and to collect data vital to epidemiological and diagnostic investigations in order to resolve such questions as dose-response relationships in blood diseases caused by exposure to benzene. Furthermore, these records are useful for the employer by enabling him to identify areas of his operations where there is or may be a problem. Exposure measurement records assist in pinpointing those processes or operations which require additional efforts to reduce exposure to benzene. Medical records provide an awareness of the incidence of industrial illness in the employer's establishment and assist the employer to focus on any aspect of his operation which may materially impair the health of his employees. The required records are also useful to the employee: Exposure records assure employees that their exposure to benzene is being monitored and also inform them of the hazards to which they are exposed; medical records assist their examining

physician to accurately diagnose and treat any health problem and assure proper evaluation of their health.

The standard specifies the information which must be included in the record. The exposure measurement record must include information which accurately reflects the exposure of each individual employee. The medical record must include the work history of each individual employee and information accurately reflecting his health. A few participants disputed the need for the content of some of these records. One comment suggested deletion of the requirement in paragraph (l)(1)(i)(b) to include as part of the exposure record a description of sampling on the ground that it is the same requirement as in paragraph (l)(1)(i)(a) for a description of the sampling procedure used to determine representative employee exposure. (Com. 76) This participant has misunderstood these requirements. The "description of sampling" in subparagraph (b) refers to the type of equipment used for collecting the concentrations of benzene, the rate at which these samples were collected and the minimum period during which the collection took place. The "sampling procedure" referred to in subparagraph (a) refers to the criteria or method used by the employer to determine that the samples he has taken are representative of the particular employee's exposure. Although these paragraphs are directed to different requirements, OSHA has eliminated from subparagraph (a) of this provision the word "sampling" in order to avoid such confusion on the part of other employers.

Another comment expressed the view that requiring employers to include in the record all of the information provided to the examining physician is an undue administrative burden (Com. 59). Where the information is communicated in writing to the doctor who will examine the employee, the employer can meet his requirement by simply retaining in his files a copy of this communication. Where, however, the information is not furnished in writing, it is

essential to record it to assure that the examining physician has been advised of all the information needed for evaluation of the employee's health. Moreover, since this information includes exposure conditions and symptoms, the information is most useful not only to the current examining physician but also to a physician who years later evaluates the health of the employee. OSHA, therefore, has retained in the standard the requirement to record the information provided to the examining physician.

An industry comment pointed out that it is not necessary for the company physicians, who maintain the medical records on behalf of the employer, to retain a copy of the regulation and its appendices as part of the record of each individual employee, but that retention of one master copy in the files would be sufficient if there is a reference to it in each employee's file (Com. 46). OSHA agrees that retention of the regulation and appendices in each employee's file unnecessarily increases the space needed for the records and, accordingly, has given employers the option in the final standard of either including the regulation and appendices in each employee's file or of retaining a master copy of these documents and referencing them in each employee's medical file.

Some industry participants testified that their facilities would need additional record clerks to maintain the information in the required records (TR 3165-3171). In view of the reduction in the final standard of the number of employees for whom exposure and medical monitoring must be conducted and reduction of the frequency rate suggested by the proposal, the need for additional recordkeeping personnel is significantly reduced. Furthermore, since the standard does not require the use of any particular form for maintaining the prescribed information, employers may incorporate these records into already existing recordkeeping systems, some of which are computerized, and thus further minimize the need for additional personnel.

The standard requires that the exposure measurement records and medical surveillance records be maintained by the employer for at least 40 years or for the duration of employment plus twenty years, whichever is longer. Several participants objected to the length of this retention period. One comment expressed the view that the retention period was unnecessarily burdensome where the only exposure to benzene is from liquid products containing small amounts of benzene (Com. 55). Both because there is no known safe level for exposure to benzene and because there is no direct linear correlation between the percentage of benzene in a liquid mixture and exposure levels, OSHA feels that there is no basis for different retention requirements based on the amount of benzene in liquids. Moreover, in view of the provision for an action level in the final standard, the number of exposure measurements and medical examinations which must be recorded will be greatly minimized where the small amounts of benzene actually do result in exposures below the action level.

Another comment suggested that the retention period for the medical surveillance records is unreasonably long (Com. 59). OSHA is aware of the burden of keeping both the medical and the exposure records for this length of time. However, OSHA feels that it is essential that the records be retained for this period. The record evidence establishes that the latency period for benzene induced leukemia is unknown (Ex. 2B-283, p. 4) and that, as in the case of other chemical carcinogens, the symptoms of carcinogenesis—in this case, benzene induced leukemia—may not appear for many years after the initial exposure (Tr. 385, 391, 410-11, 424). The retention period of forty years has, therefore, been selected to assure that the entire latency period would be covered. Furthermore, as stated in OSHA's standard for Coke Ovens Emissions (41 FR 46782), OSHA believes that it is essential to scientific investigations that exposure and medical records be maintained for the same length of time,

and that the retention period for these records be at least forty years.

One comment suggested that independent contractors, who customarily hire employees only for temporary work at a particular facility, be allowed to send the medical records to the Director of NIOSH upon expiration of the employee's employment (Com. 63). As is noted below, it is OSHA's policy for all employers that the records be maintained at the place of employment so long as it is in existence.

The standard does not require that the employer, on any regular basis, send copies of his records to OSHA. The employer is, however, required upon request to make the records available for examination and copying to designated representatives of OSHA and NIOSH. This requirement is necessary both for compliance purposes and for scientific investigations. Records of required exposure monitoring are, in addition, to be made available, for examination and copying, to current employees and their representatives; and exposure monitoring records indicating their own exposure must be made available to former employees or their designated representatives. One participant suggested deletion of the reference to the term "or their designated representative" (Com. 48) thus restricting access to appropriate exposure records only to the current or former employee himself. OSHA is of the view that denying access to the records of individual exposure by designated representaatives could result in a denial of access to the information by the employee where he is incapacitated and unable to inspect the records or simply not able to understand them. This would defeat the purpose of the availability provision which is to assure current employees that their exposure is properly monitored and assure former employees of access to information necessary for the continued protection of their health. Furthermore, the Act recognizes (sections 2(b)(13); 8(c)(3); 8(f)(1)) the legitimate role of em-

ployee representatives in occupational safety and health. One industry comment suggested that employee representatives be formally designated in writing and that access to records also be requested in writing (Com. 15). OSHA does not deem it necessary to include such a requirement in the standard, but employers may establish procedures for access to records so long as the procedures do not restrict the employees' and former employees' to access.

The standard also requires that medical records also be made available, upon request, for examination and copying to the designated physicians or representative of both current and former employees. Some comments questioned the fact that the standard enables not only the employer but also the employee and his representative and OSHA and NIOSH to have access to medical records without specifying confidentiality or otherwise limiting circulation of the information (Com. 26, 48). OSHA recognizes that a physician's records may contain a wide range of personal and medical information deemed to be confidential or private. For this reason, the standard limits the contents of the medical record to such information as is related to benzene exposure. Indeed, the standard requires in paragraph (i)(6)(ii) that the employer advise the physician that the physician's opinion, which becomes a part of the medical record, should not reveal findings or diagnoses unrelated to occupational exposure. The need of the employer, the employee and OSHA and NIOSH to have access to this information has already been thoroughly discussed. Disclosure of the information to other persons is, of course, subject to protective requirements of any applicable laws or regulations.

To assure that the records will be preserved for the required retention period of forty years, the standard requires an employer, who ceases to do business, to transfer his records to his successor and, in the event that there is no successor, to transfer the records to the Director of NIOSH.

One industry comment suggested that this section be deleted. (Com. 59). Allowing employers to dispose, at will, of the records of exposure measurements and medical surveillance would result, more often than not, in destruction of these records thus depriving employees of information necessary for evaluation of their health, as well as depriving NIOSH of information valuable to its scientific investigations.

Another participant suggested elimination of the requirement that the records be transferred to NIOSH by registered mail (Com. 68). OSHA has adopted this suggestion and the permanent standard eliminates the requirement to use registered mail.

Reports: paragraphs (d)(3), (e)(5), (f)(2), (i)(4)(i). The standard imposes notification requirements upon employers. This requirement is discussed above under *Regulated Areas.*

The standard also obligates the employer to give certain information to employees. The employer must notify each employee of the exposure measurement representative of his exposure. This notification must be made regardless of what the exposure level of the employee is. Two comments suggested that availability of exposure records was sufficient to inform employees of the results of their monitoring (Com. 46; Com. 53). Several comments suggested that the notification be required only where the employees' exposure is above the permissible exposure level (Com. 10, 15, 21, 41, 46, 53, 59) and that exposures below the permissible level be available to the employee upon request (Com. 10). OSHA believes that, consistent with section 8(c)(3) of the Act, every employee has the right to know what his exposure level is and whether it is above or below the permissible exposure level. Moreover, since the permissible exposure level is a feasibility level and not a "safe" level, the employee must know, for proper evaluation of his health by a physician in the present and future, the level of benzene

to which he is exposed. Accordingly, the suggestions to modify the employee notification requirements have not been adopted.

The standard further requires that, where the employee's exposure is over the permissible exposure level, the employer must also state in the notification what corrective action the employer is going to take to reduce the exposure level. This is necessary to assure employees that the employer is making every effort to furnish them with a safe and healthful work environment, and implements section 8(c)(3) of the Act.

Notification to employees of their exposure levels must be made in writing. Several comments objected to this requirement. Some comments suggested that the employer be permitted to notify employees by posting of a notice on the workplace bulletin board (Com. 15, 49, 59), thus relieving the employer of the burden of notifying each and every employee. It is OSHA's view that direct notification to each employee is necessary in order to assure that the employee, as required by section 8(c)(3) of the Act, is apprised of all hazards to which the employee is exposed.

The standard further requires that the notification be within five working days after receipt of the employer's measurement results. Several industry comments requested a change in the five day requirement so as to allow additional time for employers to comply (Com. 47, 49, 54, 59). OSHA feels that, under ordinary circumstances, the five day limit fulfills the statutory requirement for promptness (section 8(c)(3)) yet allows employers sufficient time for the written notification.

The standard further obligates the employer to provide the employee with a copy of the examining physician's written opinion. One industry comment pointed out the large volume of letters per year which this notification would entail (Com. 53). However, in view of the necessity

for each employee to have an evaluation of his health, OSHA is of the view that furnishing each employee with a copy of the physician's letter is not unreasonably burdensome.

Written compliance programs are also required by the standard. These are discussed above under *Methods of Compliance*. The employer is required to submit his compliance program, on request, to OSHA and NIOSH. Additionally, he must make this program available at the worksite for examination by OSHA and NIOSH and by his employees or their authorized representatives. One participant suggested that employers be required to give to each employee a notice of availability of the compliance program rather than merely making it available to the employee or his representative. OSHA feels that this would place an unnecessary burden upon the employer, and has not incorporated the suggestion.

Observation of monitoring: paragraph (m). The final standard requires that the employer provide affected employees or their designated representatives with an opportunity to observe the measuring of employee exposures. This opportunity is specifically required by section 8(c)(3) of the Act. The standard also sets forth certain procedures which must be complied with in connection with the observation of the monitoring. These procedures are designed to assure that the right to observe is meaningful and that the health and safety of the observer is protected during the observation.

A few industry participants requested that the observation of monitoring provision be deleted from the standard (Com. 65). Union participants objected to any limitations on this requirement (Grospiron statement, Ex. 11.A, p. 12). The arguments by industry were several: (1) The requirement fails to limit the number of employees who can observe the monitoring; (2) it increases the employer's costs of monitoring; (3) employees lose time from their jobs;

(4) it exposes employees to additional hazards; (5) it increases the liability potential for non-employees who are injured while observing; and (6) will result in labor/management confrontations (Com. 65, 70; L.C. 4). In view of the statutory mandate that "regulations shall provide employees or their representatives with an opportunity to observe such monitoring or measureing," OSHA has not adopted the suggestions to delete this provision.

One comment suggested that a one-time limit on observation of monitoring be established for each employee (Com. 60). OSHA has not adopted this suggestion since the statute does not impose any such limit and it does not appear to be reasonable. For example, a requirement to this effect would prohibit an employee or his representative who has observed the original monitoring to observe the redetermination of exposure which is required by the standard after a process or control change.

Effective Date

In order to assure that affected employers and employees will be informed of the existence of the provisions and terms of this standard, and that employers and employees are given an opportunity to familiarize themselves with any new requirements, the effective date of this standard will be March 13, 1978. Until such date, 29 CFR 1910.1000. Table Z-2 will continue to apply to those operations covered by the new 29 CFR 1910.1028. Subsequent to that date, 29 CFR 1910.1000, Table Z-2 will continue to apply to all operations exempted under the new 29 CFR 1910.1028.

Appendices

Three appendices have been included in this permanent standard. These appendices have been included primarily for information purposes. None of the statements contained therein should be construed as establishing a mandatory requirement not otherwise imposed by the standard or as

detracting from an obligation which the standard does impose.

The information contained in Appendices A and B is designed to aid the employer is complying with requirements of the standard. The information in Appendix C primarily provides information needed by the physician to evaluate the results of the medical examination. Appendix C also lists other types of examinations, not required by the standard, which may help the physician in making an accurate assessment as to whether continued exposure to benzene will place the employee at an increased risk. It should be noted that paragraph (j)(1)(i) and (iv) specifically require that the information contained in Appendices A and C be provided to employees as part of their information and training program.

Some suggestions were made by participants regarding the contents of these appendices. One participant suggested that Appendix A, Part III-A include the requirement as to frequency of change of respirator cartridges and canisters (Com. 8). OSHA has not adopted this suggestion since the requirement is clearly set forth in the standard, and the employer is required as part of the training program to give each employee a copy of the standard. Another participant (Com. 59) suggested that Appendix A, I, B2 state that eye contact and repeated skin contact "be avoided" instead of "prohibited." OSHA does not agree since the standard prohibits such contact. This same participant suggested that the last sentence of Appendix A, IV, A be changed to indicate that medical assistance should be sought only if irritation of eye or face persists. This limitation has not been added for the reason that OSHA feels that the more conservative advice imparted by the proposed paragraph better alerts the employees to the possible hazards of this type of exposure. The third suggestion of this participant was that Appendix A state that "medical assistance" be sought rather than that "a doctor" be called

when large quantities of benzene are breathed. A modification of this suggestion has been adopted and it is now recommended that medical assistance or a doctor be called for as soon as possible.

VII. Authority

This document was prepared under the direction of Eula Bingham, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue N.W., Washington, D.C. 20210.

Accordingly, pursuant to sections 4(b)(2), 6(b), 6(c) and 8(c) of the Occupational Safety and Health Act of 1970 (84 Stat. 1592, 1593, 1596, 1596, 29 U.S.C. 653, 655, 657), the specific statutes referred to in section 4(b)(2), Secretary of Labor's Order No. 8-76 (41 FR 25059), and 29 CFR Part 1911, Part 1910 of Title 29, Code of Federal Regulations, is hereby amended by deleting the emergency temporary standard for occupational exposure to benzene at § 1910.1028 and adding a new permanent standard for occupational exposure to benzene as § 1910.1028, and by amending Table Z-2 of § 1910.1000. In addition, pursuant to section 4(b)(2) of the Act (84 Stat. 1592; 29 U.S.C. 653), OSHA has determined that this new standard in § 1910.1028 is more effective than the corresponding standards now in Subpart B of Part 1910, and in Parts 1915, 1916, 1917, 1918, and 1926 of Title 29, Code of Federal Regulations. Therefore, these corresponding standards are superseded by this new § 1910.1028. This determination, and the application of the new standard to the maritime and construction industries, are implemented by adding a new paragraph (c) to § 1910.19 and by revoking § 1910.20.

Signed at Washington, D.C., this 31st day of January, 1978. These amendments are effective on March 13, 1978.

Eula Bingham,
Assistant Secretary of Labor.

APPENDIX D

Part 1910 of Title 29 of the Code of Federal Regulations is hereby amended by adding a new paragraph (a)(2)(iii) and a new paragraph (k)(2)(iii) to § 1910.1028 to read as follows:

§ 1910.1028 Benzene.

(a) *Scope and application.* * * *

(2) This section does not apply to:

* * * * *

(iii) Work operations where the only exposure to benzene is from liquid mixtures containing 0.5 percent (0.1 percent after June 27, 1981) or less of benzene by volume, or the vapors released from such liquids.

* * * * *

(k) *Signs and labels.* * * *

(2) The employer shall assure that caution labels are affixed to all containers of benzene and of products containing any amount of benzene, except:

* * * * *

(iii) Liquid mixtures containing 5.0 percent or less benzene by volume which were packaged before June 27, 1978. 43 Fed.Reg. 27971.

APPENDIX E

United States Court of Appeals

Nos. 78-1988, 78-1989, 78-2642, 78-2779, and 78-3023

THE AMERICAN PETROLEUM INSTITUTE, AND THE NATIONAL PETROLEUM REFINERS ASSOCIATION, ET AL.,
Petitioners

VERSUS

OCCUPATIONAL SAFETY AND HEALTH ADMINSTRATION;
UNITED STATES DEPARTMENT OF LABOR;
DR. EULA BINGHAM, AS ASSISTANT SECRETARY OF LABOR;
AND F. RAY MARSHALL, AS SECRETARY OF LABOR,
Respondents

Petitions for Review of an Order of the Occupational Safety and Health Administration (Louisiana Case)

ORDER:

The court sua sponte orders that the above causes be consolidated with cause no. 78-1253, A.P.I., et al. v. OSHA, et al.

United States Circuit Judge

APPENDIX F

United States Court of Appeals

FOR THE FIFTH CIRCUIT

October Term, 19

Nos. 78-1253, 78-1257, 78-1486, 78-1676, 78-1677, 78-1707, 78-1745, 78-1988, 78-1989, 78-2642, 78-2779, and 78-3023
OSHA No. 77-1395

THE AMERICAN PETROLEUM INSTITUTE ET AL.,
Petitioners,

THE MANUFACTURING CHEMISTS ASSOCIATION AND THE CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION,
Intervenors,

v.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION ET AL.,
Respondents,

INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
Intervenor.

Petitions for Review of an Order of the Occupational Safety and Health Administration

Before COLEMAN, CLARK AND TJOFLAT, Circuit Judges.

JUDGMENT

These causes came on to be heard on the petitions of the American Petroleum Institute, et al., and were argued by counsel;

ON CONSIDERATION WHEREOF, It is now here ordered and adjudged by this Court that the petitions for

review of an order of the American Petroleum Institute, et al., in this cause be, and the same are hereby granted; the provisions of the order reducing the airborne permissible exposure limit and the dermal contact prohibition are set aside and the remaining provisions of the standard in this cause be and the same are hereby vacated.

It is further ordered that respondents pay to petitioners the costs on appeal to be taxed by the Clerk of this Court.

October 5, 1978

Issued As Mandate:

Supreme Court, U. S.
FILED
MAY 18 1979
MICHAEL RODAK, JR., CLERK

APPENDIX

In the Supreme Court of the United States

OCTOBER TERM, 1979

Nos. 78-911 and 78-1036

INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
Petitioner

—*v.*—

AMERICAN PETROLEUM INSTITUTE, ET AL.

RAY MARSHALL, SECRETARY OF LABOR,
Petitioner

—*v.*—

AMERICAN PETROLEUM INSTITUTE, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

PETITIONS FOR A WRIT OF CERTIORARI FILED DECEMBER 7, 1978 (NO. 78-911) AND DECEMBER 26, 1978 (NO. 78-1036)
CERTIORARI GRANTED FEBRUARY 21, 1979

In the Supreme Court of the United States

OCTOBER TERM, 1979

Nos. 78-911 and 78-1036

INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
Petitioner

—*v.*—

AMERICAN PETROLEUM INSTITUTE, ET AL.

RAY MARSHALL, SECRETARY OF LABOR,
Petitioner

—*v.*—

AMERICAN PETROLEUM INSTITUTE, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

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** Diagrams and graphs in this and other studies were omitted in printing but are available in the administrative record on file with the Clerk.

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[Title of court omitted in printing]

AMERICAN PETROLEUM INSTITUTE ET AL. v. OSHA ET AL., NO. 78-1253

Feb. 2, 1978 Petition for review

March 13, 1978 Order granting motion of Manufacturing Chemists Association, The American Iron And Steel Institute, and Chemical Specialties Manufacturers for leave to intervene. (LRM) (Also filed in 78-1257).

March 21, 1978 Order granting motion of the Industrial Union Department, AFL-CIO to intervene (Also filed in 78-1257).

April 18, 1978 Order continuing temporary stay entered on 3/13/78 pending disposition of petitions for review. Further granting motion of Independent Petroleum Association of America for leave to intervene. Further petitioners' motion to consolidate is granted.[*] Further the motion to dismiss petition of review filed by Am. Petroleum in No. 77-1973, API, et al v. OSHRC is carried with the case. Further the motion to correct captions in 78-1253 and 78-1257 is granted.

June 22, 1978 Case argued.

June 23, 1978 Respondents' letter dtd 6/22/78 with copy of amendments to the benzene standard issued June 27, 1978. (CE) (Also filed in consolidated cases).

June 30, 1978 Petitioners' letter dtd 6/30/78 with "producer" petitioners' supplemental memorandum which addresses amendment to benzene standard and copy of Federal Register notice announcing amendment. (CE) (Also filed in consolidated cases).

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[*] This order consolidated cases nos. 78-1253, 1257, 1486, 1676, 1677, 1707, 1745, and any other cases seeking review of the benzene standard later transferred to the Fifth Circuit.

July 7, 1978 Order granting motion of petitioners, the Rubber Manufacturers Association, Inc., et al and the Armstrong Rubber Company, et al. to filed amended petitions for review. (JPC-CC-GBT).

July 11, 1978 Filing Secretary of Labor's motion to adjourn present supplemental briefing schedule and to set new briefing schedule on the merits of the amendment to the benzene standard.

July 12, 1978 Filing Response of Rubber Companies and Du Pont in opposition to motion to adjourn briefing schedule, etc.

July 14, 1978 Order denying the Secretary of Labor's motion to adjourn present supplemental briefing schedule. Court does not desire briefs designed to enable it to reach the merits of the new standards. (CC) (Also filed in consolidated cases).

August 4, 1978 Filing Motion of Manufacturing Chemists Association petitioner in No. 78-1988, to file amended petition for review. (Filed in consolidated cases).

August 4, 1978 Filing contingent motion of Manufacturing Chemists Association to defer briefing dates on the merits of the liquid mixture exemption amendment to the benzene standard. (Also filed in consolidated cases).

August 7, 1978 Filing motion of the American Iron and Steel Institute to file amended petition for review in No. 78-1745. (Also filed in consolidated cases).

August 7, 1978 Filing motion of the American Iron and Steel Institute to defer briefing on the merits of the liquid mixture exemption amendment to the benzene standard (Also filed in consolidated cases).

August 11, 1978 Order granting motion of the Manufacturing Chemists Association to file an amended petition for review; further order granting the contingent motion of Manufacturing Chemists Association to defer briefing on the merits of the liquid mixture exemption amendment to the benzene standard (CC) (Also filed in consolidated cases).

August 11, 1978 Order granting motion of the American Iron and Steel Institute to file amended petition for review in No. 78-1745; further order granting motion of American Iron and Steel Institute to defer briefing on the merits of the liquid mixture exemption amendment to the benzene standard. (CC) (Also filed in consolidated cases).

August 14, 1978 Motion of E. I. Du Pont de Nemours & Co. to file amended petition for review. (Also filed in consolidated cases).

August 18, 1978 Order granting motion of E.I. DuPont de Nemours and Company to file an amended petition for review.

October 5, 1978 Opinion and Judgment.

THE AMERICAN PETROLEUM INSTITUTE AND THE NATIONAL PETROLEUM REFINERS, ET AL. v. OSHA ET AL., NO. 78-1257

[The relevant docket entries for No. 78-1257 are the same as for No. 78-1253 except that the petition for review was filed a day later (February 3, 1978) and the docket for No. 78-1257 omits the entries for April 18 and July 7, 1978, shown above for No. 78-1253.]

THE RUBBER MANUFACTUERS ASSOCIATION, INC., ET AL. v. EULA BINGHAM, ET AL., NO. 78-1486

March 6, 1978 Petition to review and set aside an order of the Assistant Secretary of Labor for OSHA filed [in the Sixth Circuit, No. 78-3114].

March 9, 1978 Order granting motion of petitioners to transfer this cause to the United States Court of Appeals for the Fifth Circuit.

[After transfer, the Fifth Circuit renumbered the case No. 78-1486 and made the following entries:]

March 13, 1978 Filing order of the Sixth Circuit transferring their docket No. 78-3114 to the 5th Circuit.

April 11, 1978 Order granting motion of the Industrial Union Department, AFL-CIO, to intervene. (LRM) (Also filed in 78-1676, 78-1677, and 78-1707).

May 5, 1978 Filing respondents' motion to reschedule argument. Denied JPC.

June 22, 1978 Case argued.

June 23, 1978 Filing respondents' letter dtd 6/22/78 with copy of amendments to the benzene standard issued June 27, 1978. (CE) (Also filed in consolidated cases).

June 27, 1978 Filing motion of petitioners in Nos. 78-1486 and 78-1677 to file amended petitions for review.

June 30, 1978 Filing petitioners' letter dtd 6/30/78 with "producer" petitioners' supplemental memorandum which addresses amendment to benzene standard and copy of Federal Register Notice announcing amendment. (CE) (Also filed in consolidated cases).

July 7, 1978 Order granting motion of petitioners, the Rubber Manufactuers Association, Inc, et al, and the Armstrong Rubber Company et al, to file amended petitions for review. (JPC-CC-GBT) (Also filed in 78-1677).

July 11, 1978 Filing Secretary of Labor's motion to adjourn present supplemental briefing schedule, and to set new briefing schedule on the merits of the amendment to the benzene standard.

July 14, 1978 Order denying the Secretary of Labor's motion to adjourn present supplemental briefing schedule. Court does not desire briefs designed to enable it to reach the merits of the new standards. (CC).

July 24, 1978 Order granting motion of Chemical Specialities Manufacturers Association for leave to intervene (CC).

August 4, 1978 Filing motion of Manufacturing Chemists Association, petitoner in No. 78-1988, to file amended petition for review. (Also filed in consolidated cases).

August 4, 1978 Filing contingent motion of Manufacturing Chemists Association to defer briefing dates on the merits of the liquid mixture exemption amendment to the benzene standard. (Also filed in consolidated cases).

August 7, 1978 Filing motion of the American Iron and Steel Institute to file amended petition for review in No. 78-1745. (Also filed in consolidated cases).

August 7, 1978 Filing motion of American Iron and Steel Institute to defer briefing on the merits of the liquid mixture exemption amendment to the benzene standard. (Also filed in consolidated cases).

August 11, 1978 Order granting motion of the Manufacturing Chemists Association to file an amended petition for review; further order granting the contingent motion of Manufacturing Chemists Association to defer briefing on the merits of the liquid mixture amendment to the benzene standard. (CC) (Also filed in consolidated cases).

August 11, 1978 Order granting motion of the American Iron and Steel institute to file amended petition for review in No. 78-1745; further order granting motion of American Iron and Steel Institute to defer briefing on the merits of the liquid mixture exemption amendment to the benzene standard. (CC) (Also filed in consolidated cases).

August 18, 1978 Order granting motion of E.I. duPont de Nemours and Company to file an amended petition for review. (Also filed in consolidated cases).

October 5, 1978 Opinion and Judgment.

E. I. DU PONT DE NEMOURS & CO. v. OSHA ET AL., NO. 78-1676

March 10, 1978 Petition for review of an order of the Occupational Safety and Health Administration, U.S. Department of Labor, received March 10, 1978, filed [in the Third Circuit, No. 78-1290]. (10 cc) Service attached.

March 31, 1978 Order (Aldisert and Adams, C.J.) granting the motions by petitioner for expedited consideration of "petitioner's Motion for Transfer" *and* to transfer Petition for Review to the United States Court of Appeals for the Fifth Circuit filed.

[After transfer, the Fifth Circuit renumbered the case No. 78-1676 and made the following entries:]

April 3, 1978 Filing Order of the Third Circuit transferring their docket No. 78-1290 to the 5th Circuit.

April 11, 1978 Order granting motion of the Industrial Union Department, AFL-CIO, to intervene. (LRM). (Also filed 78-1486, 78-1677 & 78-1707).

May 5, 1978 Filing Respondents' motion to reschedule argument. Denied JPC.

June 22, 1978 Case argued.

June 23, 1978 Filing respondents' letter dtd 6/22/78 with copy of amendments to the benzene standard issued June 27, 1978. (CE) (Also filed in consolidated cases).

June 30, 1978 Filing petitioner's letter dtd 6/30/78 with "producer" petitioners' supplemental memorandum which addresses amendment to benzene standard and copy of Federal Register Notice announcing amendment. (CE) (Also filed in consolidated cases).

July 11, 1978 Filing Secretary of Labor's motion to adjourn present supplemental briefing schedule, and to set new briefing schedule on the merits of the amendment to the benzene standard.

July 14, 1978 Order denying the Secretary of Labor's motion to adjourn present supplemental briefing schedule. Court does not desire briefs designed to enable it to reach the merits of the new standards. (CC) (Also filed in consolidated cases).

August 4, 1978 Filing motion of Manufacturing Chemists Association, petitioner in No. 78-1988, to file amended petition for review. (Also filed in consolidated cases).

August 4, 1978 Filing contingent motion of Manufacturing Chemists Association to defer briefing dates on the merits of the liquid mixture exemption amendment to the benzene standard. (Also filed in consolidated cases).

August 7, 1978 Filing motion of the American Iron and Steel Institute to file amended petition for review in No. 78-1745. (also filed in consolidated cases).

August 7, 1978 Filing motion of American Iron and Steel Institute to defer briefing schedule on the merits of the liquid mixture exemption to the benzene standard. (Also filed in consolidated cases).

August 11, 1978 Order granting motion of the Manufacturing Chemists Association to file an amended petition for review; further order granting the contingent motion of Manufacturing Chemists Association to defer briefing on the merits of the liquid mixture exemption amendment to the benzene standard (CC) (Also filed in consolidated cases).

August 11, 1978 Order granting motion of the American Iron and Steel Institute to file amended petition for review in No. 78-1745; further order granting motion of American Iron and Steel Institute to defer briefing on the merits of the liquid mixture exemption amendment to the benzene standard (CC) (Also filed in consolidated cases).

August 18, 1978 Order granting motion of E.I. Du Pont de Nemours & Co. to file an amended petition for review. (Also filed in consolidated cases).

October 5, 1978 Opinion and Judgment.

THE ARMSTRONG RUBBER COMPANY AND UNIROYAL, INC. v. EULA BINGHAM, ET AL., NO. 78-1677

March 6, 1978 Filed Petition for review [in Second Circuit No. 78-4034].

March 27, 1978 Filed Order granting motion to transfer to the United States Court of Appeals for the Fifth Circuit.

[After transfer, the Fifth Circuit renumbered the case No. 78-1677 and made the following entries:]

April 3, 1978 Filing Order of the Second Circuit transferring their docket No. 78-4034 to the 5th Circuit.

[The remainder of the relevant docket entries made by the Fifth Circuit in No. 78-1677 are identical to those beginning April 11, 1978, by the Fifth Circuit in No. 78-1676.]

INDEPENDENT PETROLEUM ASSOCIATION OF AMERICA v. OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, U.S. DEPARTMENT OF LABOR, ET AL., NO. 78-1707

1978 Petition for review filed.

[The remainder of the relevant entries for No. 78-1707 are identical to those shown for No. 78-1676 beginning with the entry for April 11, 1978, with the exception that the docket in No. 78-1707 omits the entry for July 11, 1978.]

AMERICAN IRON AND STEEL INSTITUTE, ET AL. v. OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, U.S. DEPARTMENT OF LABOR, ET AL., NO. 78-1745

April 3, 1978 Petition for Review of an order of the Occupational Safety and Health Administration United States Department of Labor, received April 3, 1978, filed [in the Third Circuit as No. 78-1388]. (6 cc) Service attached.

April 7, 1978 Order (*Aldisert* and Adams, C.J.) granting petitioners' motion for transfer of Petition for Review to the United States Court of Appeals for the Fifth Circuit, filed.

[After transfer, the Fifth Circuit renumbered the case No. 78-1745 and made the following entries:]

April 10, 1978 Filing Order of the Third Circuit transferring their docket no. 78-1388 to the 5th Circuit.

[The remainder of the relevant entries for No. 78-1745 are identical to those shown for No. 78-1676, beginning with the entry for May 5, 1978, with the exception that the docket in No. 78-1745 omits the entry for July 11, 1978.]

MANUFACTURING CHEMISTS ASSOCIATION v. OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, ET AL., NO. 78-1988

March 30, 1978 Petitioner's petition for review of an order of the Occupational Safety and Health Administration (m-30) [filed in the United States Court of Appeals for the District of Columbia Circuit, No. 1287].

May 5, 1978 Per curiam order granting petitioner's motion to transfer this case to the Fifth Circuit; Bazelon and Leventhal, CJ's.

[After transfer, the Fifth Circuit renumbered the case No. 78-1988 and made the following entries:]

May 8, 1978 Filing order of the District of Columbia Circuit transferring their docket No. 78-1287 to the Fifth Circuit.

June 22, 1978 Case argued.

June 30, 1978 Filing petitioners' letter dtd 6/30/78 with "producers" petitioners' supplemental memorandum which addresses amendment to benzene standard and copy of Federal Register Notice announcing amendment. (CE) (Also filed in consolidated cases.)

July 14, 1978 Order denying the Secretary of Labor's motion to adjourn present supplemental briefing schedule. Court does not desire briefs designed to enable it to reach the merits of the new standards. (CC) (Also filed in consolidated cases).

[The remainder of the entries for No. 78-1988 are identical to those beginning with August 4, 1978, for No. 78-1676, except that the docket for No. 78-1988 omits the entry for August 11, 1978, granting motion of AISI to file amended petition and to defer briefing on amendment.]

INDEPENDENT PETROLEUM ASSOCIATION OF AMERICA v. OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION ET AL., NO. 78-1989

April 4, 1978 Petitioners' petition for review of an order of the OSHA (m-4) [filed in the United States Court of Appeals for the District of Columbia Circuit, No. 1308].

May 3, 1978 Per Curiam Order granting Petitioners' motion for transfer and this case is transferred to the Fifth Circuit: Bazelon and Leventhal, CJ's.

[After transfer, the Fifth Circuit renumbered the case No. 78-1989, and made the following entries:]

May 8, 1978 Filing Order of the District of Columbia Circuit transferring their docket no. 78-1308 to the 5th Circuit.

June 22, 1978 Case argued.

July 14, 1978 Order denying the Secretary of Labor's motion to adjourn present supplemental briefing schedule. Court does not desire briefs designed to enable it to reach the merits of the new standards. (CC) (Also filed in consolidated cases).

August 18, 1978 Order granting motion of E.I. Du Pont de Nemours & Co. to file an amended petition for review. (Also filed in consolidated cases)

October 5, 1978 Opinion and Judgment.

November 1, 1978 Order consolidating this appeal with 78-1253, et al (CC).

INDUSTRIAL UNION DEPARTMENT, AFL-CIO v. DR. EULA BINGHAM, ET AL., NO. 78-2642

July 11, 1978 Petitioner's petition for review of order of the Dept. of Labor (p-10) [filed in the United States Court of Appeals for the District of Columbia Circuit, No. 1644].

July 26, 1978 Per curiam order granting petitioner's motion to transfer and this case is to be transferred to the USCA for the 5th Circuit as promptly as the business of office permits; CJ Wright and McGowan, CJ.

[After transfer, the Fifth Circuit renumbered the case No. 78-2642 and made the following entries:]

August 1, 1978 Filing order of the District of Columbia Circuit transferring their docket no. 78-1644 to the 5th Circuit.

August 18, 1978 Order granting motion of E. I. Du Pont de Nemours & Co. to file an amended petition for review. (Also filed in consolidated cases).

October 5, 1978 Opinion and judgment.

November 1, 1978 Order consolidating this appeal with 78-1253 et al (CC).

THE AMERICAN PETROLEUM INSTITUTE AND THE NATIONAL PETROLEUM REFINERS ASSOCIATION, ET AL. v. OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION UNITED STATES DEPARTMENT OF LABOR, ET AL, NO. 78-2779

August 18, 1978 Petition for review filed.

October 5, 1978 Opinion and judgment.

THE ADHESIVE AND SEALANT COUNCIL, INC. v. EULA BINGHAM, ET AL, NO. 78-3023

[This case was filed in the Fourth Circuit on August 18, 1978, and transferred to the Fifth Circuit on September 11, 1978. The record does not include the Fourth Circuit's docket entries but does disclose the filing and transfer dates. After transfer, the Fifth Circuit renumbered the case No. 78-3023, and made the following docket entries:]

Sept. 18, 1978 Filing Order of the Fourth Circuit transferring their docket no. 78-1544 to the Fifth Circuit.

October 5, 1978 Opinion and Judgment.

November 1, 1978 Order consolidating this appeal with 78-1253 et al. (CC).

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 78-1253

THE AMERICAN PETROLEUM INSTITUTE, ET AL.,
PETITIONERS

v.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION,
RESPONDENTS

PETITION FOR REVIEW

Pursuant to Section 6(f) of the Occupational Safety and Health Act of 1970, 29 U.S.C. § 655(f), The American Petroleum Institute, the National Petroleum Refiners Association on behalf of their respective members, and American Petrofina, Incorporated, Cities Service Company, Continental Oil Company, Delta Oil Company, Exxon Corporation, Gulf Oil Company, Husky Oil Company, Marathon Oil Company, Mobil Oil Corporation, Phillips Petroleum Company, Shell Oil Company, South Hampton Oil Company, Standard Oil Company (Indiana), The Standard Oil Company (Ohio), Sun Oil Company of Pennsylvania, Sun Oil Company of Delaware, Texaco Inc., Union Oil Company of California, U.S.A. Petrochem Corporation, and Williams Pipe Line Company, hereby challenge the validity of, and petition this Court for review of, the Permanent Standard for Occupational Exposure to Benzene released by the Occupational Safety and Health Administration, Department of Labor, on February 2, 1978.

The Permanent Standard for Occupational Exposure to Benzene challenged by this Petition supplants and replaces the Emergency Temporary Standard for Occupational Exposure to Benzene (42 Fed. Reg. 22516) previously challenged by the same petitioners in *American Petroleum Institute, et al.* v. *OSHA, et al.*, No. 77-1973, presently pending before this Court.

By this Petition, the above captioned petitioners also challenge OSHA's procedural regulations dealing with the official time for issuance of agency actions (29 C.F.R. § 1911.18(d), 42 Fed. Reg. 65166) on the ground that such regulations may be invalid and inconsistent with the D.C. Circuit's opinion in *Industrial Union Dept. AFL-CIO, et al.* v. *Bingham, et al.*, Nos. 77-1395, 77-1516 which retransferred *API, et al.* v. *OSHA, et al.* (No. 77-1973) to this Court.

Respectfully submitted,

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February 2, 1978.

[The following document was appended to the agency brief in the court of appeals]

CARCINOGEN ASSESSMENT GROUP'S PRELIMINARY REPORT ON POPULATION RISK TO AMBIENT BENZENE EXPOSURES

This document is being released by EPA for external review

ROY E. ALBERT, M. D.
Chairman

PARTICIPATING MEMBERS

Elizabeth L. Anderson, Ph. D.
I. Nathan Dubin, M. D.
Richard N. Hill, M.D., Ph. D.
Robert E. McGaughy, Ph. D.
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Todd W. Thorslund, Sc. D.

STAFF ASSISTANT

Claudia Slacik

[Table of Contents Omitted in Printing]

PRELIMINARY ESTIMATE OF POPULATION RISK TO AMBIENT BENZENE EXPOSURES

I *Summary*

There is substantial epidemiological evidence that benzene is a human leukemogen. However, no validated animal model has yet been developed for benzene as a carcinogen. There are several large series of case reports indicating a high risk of leukemia in individuals who developed aplastic anemia consequent to benzene exposure. In addition there are a number of epidemiological studies in the rubber and shoe industries that demonstrate an excess risk of leukemia. From the standpoint of making quantitative estimates of the leukemia risk associated with current general population exposures to benzene in the United States there are only two epidemiological studies that provide some estimates of both exposure to benzene and data on the occurence of leukemia. These studies are by Infante (3) and by Ott, et al. (5).

The Infante study, which showed an excess incidence of leukemia, is not yet completely analyzed. Hence, some assumptions have had to be made about the average duration and magnitude of exposures. For this reason, this report should be considered as preliminary. The Ott study indicated no excess leukemia risk with relatively well-documented exposures.

The results of the Infante study were used as the basis for an extrapolation of the leukemia risk to the low levels of general population exposure, which averages one part per billion (4). A linear non-threshhold model was used for the extrapolation; such a model is expected to give an upper limit to the estimated risk. Using this extrapolation model, and using the leukemia rates observed in the cohort of workers exposed to benzene over a period of about 30 years (in the Infante study), we estimated that the number of cases of acute myelogenous and myonocytic [2] leukemia per year in the general population

due to ambient atmospheric benzene is somewhere between 30 and 80 cases. The lifetime risk to an individual continually exposed to benzene at a level of 1 ppb is estimated to be between 10^{-5} and 2.5 x 10^{-5}, depending on which exposure assumptions are made in the Infante study. The risk from individual sources of benzene emissions ranges from about 10^{-6} to 5 x 10^{-5}. The Ott study, which reported no excess leukemia risk, is consistent with the Infante study on statistical grounds given their relative exposures. However, the negative results of the Ott study suggest that the level of calculated risk in the general population is not likely to be higher than 10^{-5} to 2.5 x 10^{-5}, but it could be lower.

[3] II *Introduction*

The Carcinogen Assessment Group (CAG) has been asked by the Office of Air Quality Planning and Standards (OAQPS) to estimate the carcinogenic risk to the United States population of ambient benzene concentrations. This type of information is useful in judging the overall contribution of benzene emissions to the national rates of cancer mortality, and will be used by OAQPS in the decision whether to regulate benzene.

As the primary basis for this estimation the CAG is using the Infante (Infante, et al. 1977) mortality study of workers exposed to benzene in the production of a natural rubber cast film product. The reasons for this choice are: (1) the worker exposures are said to have been almost exclusively restricted to benzene, since it is used throughout the plant as the principal solvent in all major processes; (2) the individuals in the cohort all worked before 1950 and were followed until 1975, thus allowing long latency diseases to be observed and (3) acute myelogenous leukemia was observed, which is the same cell type of leukemia observed in other studies where workers have had known benzene exposures. The disadvantages of relying on this study for determining general population risks are (1) the authors essentially give no estimate of worker exposures except to say that the levels were less than the prevailing recommended occupational limits at the time various monitoring surveys were made; (2) the cohort studied actually worked at two separate plants (Akron and St. Mary's, Ohio). Air monitoring information in the former plant is almost non-existent (Baier, 1977), and therefore the exposure to half of the members of the cohort is almost completely unknown. However, it is known (Young, 1977) that the crude rates (leukemia cases/total people in the cohort) are similar in the two [4] locations; (3) Warren et al. (1977) have claimed that over 400 workers known to be exposed to low benzene levels were deliberately excluded from the cohort.

In spite of these difficulties the Infante study is the only one currently available which reports an excess rate of leukemia among benzene-exposed populations. Another occupational study (Ott, et al. 1977) of workers exposed to benzene has documented the exposures relatively well and reports no excess leukemia risk. The risk estimates based on Infante's study are used to calculate the number of cases expected in the cohort examined by Ott, et al. If this is not significantly different than the observed number of cases, the estimates are not grossly in error. A more complete evaluation of the Infante study will be possible after the authors have made a final evaluation of their data.

III. *Description of Infante Study*

In a retrospective study of mortality among a cohort of 748 white male workers in two Ohio plants manufacturing a natural rubber cast film product, Infante, et al. (1977) observed a statistically significant higher rate of leukemia than both of two control groups. The leukemia mortality rate was 5.06 times higher than the general U. S. white male population standardized for age and time period of the cohort exposure, and 4.74 times higher than a cohort of 1447 white males employed at an Ohio fibrous-glass construction products factory. These results were based on a 75% follow-up of the vital status of the workers. A total of 160 deaths were observed and of these there were 7 leukemia deaths four of which were

acute lyelogenous, one chronic myelogenous, and two monocytic leukemia. The worker exposure information is discussed in IV B below.

[5] IV. *Analysis of Myelogenous and Monocytic Leukemia Risks due to Benzene Exposures*

A. *General Approach*

As was noted in the benzene health document (Goldstein, et al. 1977), very little information exists that can be utilized to obtain a dose response relationship between benzene and leukemia in humans or animals.

However, if a number of simplifing assumptions are made, it is possible to construct a crude dose response model whose parameters can be estimated using vital statistics, the Infante study, historical benzene workplace standards, and a recent environmental benzene exposure study. (Mara and Lee, 1977)

We assume that for low exposures the lifetime probability of death from leukemia may be represented by the linear equation

$$P = \alpha \div \beta x$$

where α is the rate in the absence of benzene exposure and x is the average lifetime exposure to atmospheric benzene expressed in ppm. The term β is the change in the leukemia rate for each increase of one ppm of benzene in the air.

From the Infante, et al. study the relative risk of leukemia for benzene workers compared to the general population was obtained. We will denote this ratio as R and make the assumption that

$$R = \frac{R_2}{R_1} = \frac{\alpha + \beta(x_1 + x_2)}{\alpha + \beta x_1}$$

where x_1 is the exposure of the general population to benzene and x_2 is the industrial exposure to benzene.

[6] From our two assumptions we have the two linear equations in two unknowns of the form

$$RR_1 = \alpha \div \beta x_1 + \beta x_2$$

$$R_1 = \alpha \div \beta x_1$$

so that

$$\beta = R_1(R\text{-}1)/x_2$$

and βx_1 is the average lifetime risk due to ambient benzene exposures.

To utilize this technique to predict risk it is necessary to obtain estimates of R_1, R, X_1, and X_2. The estimation of each of these quantities is discussed in a separate section.

B. *Estimation of Relative Risk R*

Infante, et al. (1977) established as a lower bound a total of seven acute myelogenous or monocytic cases of leukemia in their studied cohort of 748 members. They calculated an expected value of 1.3831 cases for all forms of leukemia. From the 1971 U. S. Vital Statistics (U. S. DHEW, 1971) we note that of 7,564 cases of leukemia in white males, a total of 3,260 or 43% were myelogenous or monocytic. Thus an estimate of the relative risk for acute myelogenous and monocytic leukemia in white males is

$$R = \frac{7}{1.3831 \times 0.43} = 11.77$$

[7] C. ESTIMATION OF BACKGROUND LEUKEMIA RATE R_1

The lifetime risk to a disease can be estimated from age-specific deaths rates in the following manner. We assume that during different segments of a lifespan the total and disease specific death rates are constant. we define the following terms:

αj = death rate due to a specific disease during the jth lifetime segment.

$\alpha j \div \lambda j$ = total death rate during j^{th} lifetime segment.

S_j length of jth lifetime segment.

$P_{1j} = \frac{\alpha j}{\alpha j \div \lambda j}$ = probability of death due to the specific diseaes given that death occurred during the jth lifetime segment.

$P_{2j} = 1\text{-}e\text{-}(\alpha j \div \lambda j) S_j$ = probability of death during the jth lifetime segment given survival up to the start of the jth lifetime segment.

$P_{3j} = \pi_{k=1}^{j} (1-P_{2k})$ = probability of survival until the start of the jth lifetime segment.

If we assume that the entire lifetime is divided into m mutually exclusive segments then by definition $P_{31}=1$, $P_{2m}=1$ and the entire lifetime probability of the disease is

$$P = \sum_{j=1}^{m} P_{1j} P_{2j} P_{3j}$$

[8] The age specific rates for white males for myelogenous and monocytic leukemia were estimated from the total leukemia rates by multiplying the entries in Table I-13, disease categories 204-207, white male (U. S. DHEW, 1971) by 0.43. This gives the entries j shown in Table 1. The total mortality $\alpha j + \lambda j$ is also obtained from table I-13 and is shown in Table 1. The other terms are calculated by the given definitions and the final result, the lifetime risk of white males exposed to background levels of benzene is found to be

$$R_1 = 0.38987 \times 10^{-2}$$

[9]

TABLE 1

COMPUTATION OF LIFETIME RISK OF MYELOGENOUS-MONOCYTIC LEUKEMIA

Age Intervals	Sj	αj	$\alpha j + \lambda j$	P_1	P_2	P_3	$P_1P_2P_3$
1	1	.73	1,852.8	$.3940 \times 10^{-3}$	$.1836 \times 10^{-1}$	1.	.0000072
1-4	4	1.68	79.6	$.2111 \times 10^{-1}$	$.3179 \times 10^{-1}$	.9816	.0000659
5-14	10	1.38	40.5	$.3407 \times 10^{-1}$	$.4042 \times 10^{-1}$	.9785	.0001348
15-24	10	.95	127.6	$.7445 \times 10^{-2}$	$.1268 \times 10^{-1}$	.9745	.0000920
25-34	10	1.03	155.4	$.6628 \times 10^{-2}$	$.1542 \times 10^{-1}$	.9621	.0000983
35-44	10	1.38	309.6	$.4457 \times 10^{-2}$	$.3049 \times 10^{-1}$	.9473	.0001287
45-54	10	2.58	708.7	$.3640 \times 10^{-2}$	$.6842 \times 10^{-1}$	.9184	.0002287
55-64	10	6.41	1,632.0	$.3928 \times 10^{-2}$	.15058	.8556	.0005061
65-74	10	15.57	3,586.1	$.4342 \times 10^{-2}$	.30135	.7268	.0009510
74-85	10	31.43	7,747.6	$.4057 \times 10^{-2}$	.53919	.5078	.0011108
85+		43.65	17,758.1	$.2458 \times 10^{-2}$	1.	.2340	.0005752
							.0038987

$R_1 = 0.0038987$

[10] D. ESTIMATE OF AVERAGE AMBIENT BENZENE EXPOSURE

In a recent EPA contractor report (Mara and Lee, 1977), data relating to benzene exposure in the United States was compiled. For each of several annual average concentration ranges, the population exposed to seven categories of benzene emissions was calculated. The seven categories were: (1) chemical manufacturing, (2) coke ovens, (3) gasoline service stations (separately for people using self-service stations and for people living in the vicinity of the stations), (4) petroleum refineries, (5) solvent operations, (6) storage and distribution of benzene and (7) urban exposures related to automobile tailpipe and gasoline tank emissions. The general procedure used was to start with production data for benzene or its major products, estimate emission factors (benzene release per kg of end product), apply an appropriate air dispersion model to obtain concentrations as a function of distance from the source, and to use population density information for each location to calculate the number of people exposed to each concentration range. Air monitoring data were used whenever it was available. The results are summarized in Table 2. From this data one can calculate that the annual average exposure of an individual to ambient benzene from all sources is 1.03 ppb.

[11]

TABLE 2.

SUMMARY OF POPULATIONS EXPOSED (THOUSANDS) TO ATMOSPHERIC BENZENE EMISSIONS[a]

Concentrations (ppb)	Total Population	Chem. Mfg.	Coke Ovens	Gasoline Stations		Petroleum Refineries	Solvent Operations	Urban Exposures
				Self Service	Vicinity			
0.042	37,000			37,000				
0.50	185,297	7,497	15,726		87,000	6,529	208	68,337
								45,353
1.50	77,913	970	521		31,000	64	5	
3.00	509	453	50			4	2	
7.0	646	644	2					
30.0	319	319						
	301,684							
Population Weighted Averages (ppb)	0.7514	2.0885	0.5404	0.042	0.7627	0.5112	0.5465	0.8989

Average exposure to the population of 220 million is $\frac{0.7514 \times 301{,}684 = 1.030 \text{ ppb}}{220{,}000}$

[a] Adapted from Mara and Lee (1977).

[12] E. ESTIMATION OF AVERAGE OCCUPATIONAL EXPOSURE

Information about the plant benzene levels is contained in the Appendix to the testimony of Baier at the OSHA benzene hearings (Baier, 1977).

From the opening of the factory in 1940 until 1946, no monitoring records were available. Following the installation of new ventilation equipment in 1946, a survey showed that "most areas" in the plant ranged from 0 to 15 ppm and that all areas were less than the maximum safe limit of 100 ppm which prevailed at that time. From this information, one can guess that the average exposure to all people in the plant before 1946 is probably not much more than 100 ppm, and not less than 15 ppm.

Benzene levels were monitored after 1946 at various plant locations but they were all instantaneous samples and no reliable information is available about how many man-hours were spent at those locations or whether protective masks were worn. These are case reports of exposures of 1000 ppm for short time intervals. Since the average levels were generally close to the occupational standard, we will make the assumption that the average worker exposure was the same as the prevailing recommended occupational limits. These are tabulated below along with the time weighted average for the 36 years of the total exposure period.

Time Interval	Average Exposure(ppm)	Time-Weighted Average(ppm)
1940-46 (7)	100-15	
1947 (1)	50	39.9-23.3
1948-56 (9)	35	
1957-68 (12)	25	
1969-1975(7)	10	

[13] The actual levels to which the workers were exposed was a subject of heated debate at the OSHA benzene hearings. The CAG would like to see a realistic estimate of the population weighted average exposure and its uncertainty limits. The time-weighted averages for occupational exposure must be converted to a continuous exposure life-time basis. It will be assumed that the

maximum likely lifetime exposure would result if a worker entered the factory in 1940 and was exposed to 82 ppm for 10 years and 23.7 ppm for 25 years (which is equivalent to an average of 40.36 ppm for 35 years) and the least likely exposure would occur if a worker started in 1950 and was exposed to 23.7 ppm for 25 years. Therefore the equivalent continuous lifetime exposures are:

$$\text{High estimate: } 40.36 \times \frac{240}{365} \times \frac{1}{3} \times \frac{35}{70} = 4.4 \text{ ppm}$$

$$\text{Low estimate: } 23.7 \times \frac{240}{365} \times \frac{1}{3} \times \frac{25}{70} = 1.8 \text{ ppm}$$

[14] F. CONCLUSIONS

Given the following derived estimates of our parameters of interest:

$$R = 11.77$$

$$R_1 = 0.38987 \times 10^{-2}$$

$$X_1 = 1.030 \times 10^{-3} \text{ ppm}$$

$$X_2 = 1.8 \text{ to } 4.4 \text{ ppm}$$

the parameter β and the resulting lifetime risks and expected number of acute myelogenous and monocytic leukemia deaths can be derived in the manner previously indicated. In table 3 the average risk rates and expected number of cases per lifetime and per year are shown for total benzene exposure. In Table 4 the total rates and cases are subdivided by source of exposure. We note that about 85% of the total number of cases are directly related to the use of gasoline.

It should be emphasized that due to the very crude methods that were necessarily employed in the estimation of benzene exposures by both CAG for Infante's cohort and Mara and Lee (1977) for the U.S. population, the estimates could easily be in error by several orders of magnitude. This is true even if the form of the mathematical response model used is a correct rescription of benzene induced leukemia, which is also open to question.

However, an additional independent negative study of workers exposed to benzene (Ott, et al. 1977, Dow Chemi-

cal Company) can be used to ascertain whether our model, based on Infante's data, grossly over-estimates the leukemia risk to benzene exposure. They reported the mortality [15] experience of a cohort of workers whose exposure to benzene had been carefully documented since 1940. No excess of leukemia was observed in the cohort by 1973. Since the prediction model was previously discussed based upon workers with highly uncertain exposures, it was felt to be important to estimate the number of leukemia cases we might expect in Dow's cohort if our model was valid.

Using Dow's exposure estimates and expected number of cases for its workers, it was found that our model predicted from 1.43 to 1.74 cases of leukemia where one case was actually observed. Since this estimate is well within the limits of normal statistical variability we can be confident in claiming that the Dow study does not offer any evidence upon which to question the validity of our model.

[16]

TABLE 3

TOTAL U.S. POPULATION RISKS TO BENZENE

Industrial Exposure (X_2)	$\beta = .4149 \times 10^{-1}/X_2$	Average Risk βX_1	Lifetime Exp. Leukemia Cases in U.S.	Expected Number of Cases/Year
High = 4.4 ppm	$.9609 \times 10^{-2}$	$.9897 \times 10^{-5}$	2,177	31.1
Low = 1.8 ppm	$.2399 \times 10^{-1}$	$.2471 \times 10^{-4}$	5,436	77.7*

* This represents about 1.2% of cases observed in 1971.

[17]

TABLE 4.

RISK AND LIFETIME EXPECTED NUMBER OF LEUKEMIA CASES DUE TO BENZENE EXPOSURE FOR DIFFERENT SOURCES

Source of Exposure	Average Level of Exposure ppb.	Population Exposed Millions	Risk Rates $X_2=4.4$	Risk Rates $X_2=1.8$	Lifetime Expected of Leukemia Cases $X_2=4.4$	Lifetime Expected of Leukemia Cases $X_2=1.8$
Chem. Mfg.	2.0885	9.98	$2.x10^{-5}$	$5.00x10^{-5}$	200	499
Coke Ovens	.5404	16.30	$5.19x10^{-6}$	$1.30x10^{-5}$	85	211
Self-Ser. Gas Stations	.042	37.00	$4.04x10^{-7}$	$1.01x10^{-6}$	15	37
Vicinity of Gas Stations	.7627	118.00	$7.33x10^{-6}$	$1.83x10^{-5}$	865	2,162
Petroleum Refineries	.5112	6.60	$4.91x10^{-6}$	$1.23x10^{-5}$	32	81
Solvent Operations	.5465	.22	$5.41x10^{-6}$	$1.35x10^{-5}$	1.2	3
Urban Exposures	.8989	113.69	$8.64x10^{-6}$	$2.16x10^{-5}$	982	2,456
Total	1.030	220.00*			**2,180	**5,449

* Does not sum due to multiple exposure.

** This represents about 1% of the number of cases expected in a lifetime assuming current incidence rates.

[18] REFERENCES

1. Baier, E. J. "Statement of the National Institutes of Occupational Safety and Health", Exhibit 64A, OSHA Benzene Hearings, July 19-Aug. 10, 1977.
2. Goldstein, B. D., C. A. Snyder, R. Snyder, R. and S. R. Wolman, "Review of Benzene Toxicity," prepared for EPA, August 18, 1977.
3. Infante, P. F., J. K. Wagoner, R. A. Rinsky, R. J. Young, "Leukemia in Benzene Workers," Lancet, p. 76-78, July 9, 1977.
4. Mara, S. J. and Lee, S.S., "Human Exposures to Atmospheric Benzene" EPA contract 68-01-4314 with Stanford Research Institute, September, 1977.
5. Ott, M. G., J. C. Townsend, W. A. Fishbeck, R. A. Langner, "Mortality Among Individuals Occupationally Exposed to Benzene" Exhibit 154, OSHA Benzene Hearings, July 19-August 10, 1977.
6. U. S. Department of Health, Education and Welfare. "Vital Statistics of the United States, 1971, Volume II-Mortality, Part A", Superintendent of Documents, U.S. Government Printing Office, Stock No. 017-022-00378-3.

   Warren, E. W., R. F. Van Voorhee, A. F. Sampson, "Post Hearing Brief of API, NPPA, and Individual Member Companies Regarding the Proposed Revised Permanent Standards for Occupational Exposure to Benzene", OSHA Docket No. H-059 September 22, 1977.

   Young, R. J. National Institute of Occupational Safety and Health, Personal Communication, October, 1977.

[The following document was attached to the reply brief of the American Petroleum Institute in the Court of Appeals]

AFFIDAVIT OF DR. STEVEN H. LAMM

I, Dr. Steven H. Lamm, being duly sworn, do state and depose as follows:

1. I was graduated from the University of Southern California in 1968 with the degree of Doctor of Medicine. From 1968 to 1969, I held a rotating internship at the University of Oregon. From 1969 to 1970, I held a residency in pediatrics at the Montreal Children's Hospital. From 1970 to 1972, I was employed by the United States Public Health Service as an epidemiologist attached to the Connecticut State Department of Health. From 1972 to 1973, I was Senior Pediatric Resident at the Bronx Memorial Hospital, Albert Einstein School of Medicine. From 1973 to 1974, I attended the London School of Hygiene and Tropical Medicine, in London, England. From 1974 to 1976, I was Senior Epidemiologist at the National Institute of Child Health and Human Development of the National Institutes of Health. From 1976 to 1977, I was in private practice as a pediatrician and as a consultant in epidemiology. From 1977 to the present time, I have been an associate with Tabershaw Occupational Medicine Associates.

2. I appeared as a witness for the Manufacturing Chemists Association during the hearing held last summer by the Occupational Safety and Health Administration (OSHA) on the proposed standard for occupational exposure to benzene. In the course of preparing my testimony and attending the hearing, I became thoroughly familiar with the evidence associating occupational exposure to benzene with leukemia, particularly the study conducted by Infante, *et al.*[1]

3. In December of 1977, I prepared and presented to the Environmental Protection Agency's Science Advisory Board a review and critique of the preliminary report by EPA's Carcinogen Assessment Group (CAG) entitled "Population Risk to Ambient Benzene Exposures."[2] I have the following comments on the CAG report as it compares to the risk estimate developed by Dr. Richard Wilson, presented to OSHA during the 1977 benzene hearing.[3] I have reviewed and am thoroughly familiar with both documents.

4. In its brief filed in the above-captioned case on June 8, 1978, OSHA cites the CAG's preliminary findings of 30-80 cases of leukemia from exposure to ambient levels of benzene as discrediting Dr. Wilson's analysis, which concluded that OSHA's 1 ppm standard will prevent, at most, 2 cases of cancer every six years.[4] OSHA's use of the CAG estimates, which are based on the lifetime continuous exposure of a population of 220 million people, is specious and seriously misleading as applied in the occupational context. I have performed a series of calculations (See Exhibit A) which show that the CAG's risk estimate, when translated to the occupational context, is fully consistent with—indeed, somewhat lower than—Dr. Wilson's estimate.

5. The CAG and Wilson estimates are based on risk estimates of two *different* populations with two *different* sets of exposure assumptions. The CAG estimate of 30-80 cases is an estimate of the number of cases of acute non-lymphocytic leukemia deaths that might occur annually if the USA total population of 220 million people were exposed continually throughout their lifetime, 24 hours a day, 365 day a year, to a benzene concentration of one part per billion in air.

6. The Wilson estimate of one leukemia case and one additional cancer case in 6 years is based on the assumption that for a year 30,000 workers exposed to benzene at a level between 1-10 ppm are exposed 8 hours, 240 working days a year at an average level of 3 parts per

[1] Infante, Rinsky, Wagoner & Young, *Leukemia Among Workers Exposed to Benzene* (April 28, 1977) (OSHA Exhibit 40).

[2] The CAG Preliminary Report is attached as Addendum C to OSHA's brief filed on June 8, 1978 in the above-captioned case.

[3] Testimony of Dr. Richard Wilson, Ex. 149.B.

[4] OSHA Brief 87 n.80.

million benzene in the air. The figure of 30,000 is obtained from page 1-7 of the Economic Impact Study of the proposed standard prepared by OSHA by Arthur D. Little, Inc.

7. In order to compare these estimates, they must be related to the same exposure level and time and to the same population. CAG indicates that their case numbers are based on an estimation that the lifetime (70 year) risk of leukemia due to lifetime (70 years), continuous (24 hours/day, 365 days/year) exposure to 1 ppb benzene in air is from 1 x 10^{-5} to 2.5 x 10^{-5}.[5] Wilson's case numbers derive from the assumption that 1.8 x 10^{-6} is the yearly risk of a worker dying from leukemia from having been exposed for one work year of 8 hours/day, 240 days/year to a level of 1 part per million benzene. Attached Exhibit A reviews the algebra necessary to compare the two estimates.

8. Assuming an average lifetime of years, Equation 2 divides the CAG risk by 70 and identifies the lifetime risk for *1 year*, continuous exposure to 1 ppb of benzene as [from 0.14 to 0.36] x 10^{-6}, or [from 140 to 360] x 10^{-9}. In Equation 3, I again divide by 70 to produce the *annual* risk of 1 year, continuous exposure to 1 ppb of benzene, which is [from 2.0 to 5.1] x 10^{-9}.

9. Workers do not work 24 hours a day, which is the exposure period assumed in the CAG model, but generally work only one-third of a day (8 hours). Therefore, Equation 4 divides the CAG risk by 3, to produce a risk of [from 0.7 to 1.7] x 10^{-9}, as the annual risk for 1 year of eight-hour daily exposure to 1 ppb of benzene.

10. In addition, the CAG estimate assumes exposure every day of the year, but workers do not work every day. Therefore, weekends, holidays and vacations, amounting to about one-third of the full year, must be excluded. Equation 5 accomplishes this, and shows an annual risk for 1 *work*-year of eight-hour workday exposure to 1 ppb [from 0.45 to 1.1] x 10^{-9}.

11. Finally, the CAG assumes exposure to 1 part per *billion* of benzene. To obtain the risk of exposure to 1

[5] CAG Preliminary Report, Table 3.

part per *million* of benzene, the risk must be multiplied by a factor of 1000, and Equation 6 reveals that, based on the CAG's risk estimate, the annual risk of 1 work year of eight-hour workday exposures to 1 part per million of benzene is [from 0.45 to 1.1] x 10^{-6}.

12. Thus it is shown that CAG's estimate of lifetime risk of acute non-lymphocytic leukemia (ANLL) death of [1.0 to 2.5] x 10^{-5} for lifetime continuous environmental exposure to 1 ppb benzene is equivalent to a [0.45-1.1] x 10^{-6} annual risk of ANLL death for 1 year of occupational exposure (8 hours/day, 240 days/year) to 1 ppm benzene.

13. Dr. Wilson has based his case count on an annual risk of death from *all* types of leukemia (not just ANLL) of 1.8 x 10^{-6} for one work year of occupational exposure to 1 ppm benzene. Since only 43% of leukemia deaths are due to acute nonlymphocytic leukemia, the Wilson risk can be translated into a 0.77 x 10^{-6} risk of acute nonlymphocytic leukemia death from one work year of occupational exposure to 1 ppm benzene.

14. Thus, Wilson and CAG have reached the same estimate of the annual risk of acute non-lymphocytic leukemia death due to one work year of occupational exposure to 1 ppm benzene, to wit,

CAG estimate = [from 0.45 to 1.1] x 10^{-6}
Wilson estimate = 0.77 x 10^{-6}

15. Based on the data provided in the Arthur D. Little Study, Dr. Wilson assumed that the 30,000 workers exposed to between 1 and 10 ppm are exposed to an average of 3 ppm benzene. It therefore follows, using the CAG estimate, that a reduction in these workers' exposure to benzene from 3 ppm to 1 ppm might reduce their ANLL mortality annually for each year of exposure by

(0.45 to 1.1 x 10^{-6}) x (1 work year) x (3 ppm-1 ppm) x (30,000 people) = ([0.45 to 1.1] x 10^{-6}) x 1 x 2 x 30,000 = (.027-.066) cases ANLL/year.
= one case every 15-37½ years

Use of the Wilson estimate of .77 x 10^{-6} would predict .046 excess cases ANLL each year or 1 case every 21 years.

16. Wilson's estimate of one leukemia case and one other cancer case in 6 years was based on three additional conservative assumptions.

a. *All* leukemias (not just ANLL) are benzene related.

b. For every benzene leukemia there would be another cancer at another site in the body due to benzene exposure.

c. Benzene exposure of those currently exposed to 1 to 10 ppm benzene would be far less than 1 ppm if a new standard were introduced.

There is no reason to believe the need for any of these pessimistic assumptions, but these assumptions account for the different numbers derived from the Wilson risk estimate.

17. It is concluded, based on the CAG estimate and its underlying assumptions, that reduction of occupational benzene exposure from 10 ppm to 1 ppm for each year of work might reduce the annual mortality for acute non-lymphocytic leukemia by 1 case every 15-38 years.

18. The CAG estimated range was based on the premise that the Infante cohort was exposed to a mean occupational exposure of 24-40 ppm benzene. This was based on the assumption that the exposure was at the maximum permissible exposure level in effect from time of hire in the forties to the end of study period 1975. This assumption leads to an under-estimation of the levels of exposure because: 1) industrial hygiene data show that nearly half the surveys indicated levels greater than the TLV at that time; and 2) the inclusion of exposure estimates through 1975 is inappropriate since all the leukemia deaths occurred prior to 1962 and the period of exposure necessary to inclusion in the study ended in 1949; and 3) the estimate ignores exposures prior to 1941 when no maximum exposure standard existed and during which many employees worked. Evidence in the hearing indicated that levels of exposure exceeded 100 ppm in the forties.[6] If the CAG estimates was recalculated under the assumption that the exposure was at 100 ppm (rather than 24 or 40 ppm), the risk estimate would be further reduced by 60% to a risk estimate of about 0.20×10^{-6}, which would predict that OSHA's 1 ppm standard would avoid .012 cases ANLL per year, or about one case in 83 years.

[6] See Brief of API, AISI, MCA and IPAA, the printed version of which was filed in the above-captioned case on June 13, 1978, at pp. 15-18, 36-37.

19. The purpose of this exercise has been to indicate the similarity between the risk estimates produced by CAG and by Dr. Wilson. My purpose has not been to prepare a new, independent estimate of the effect of OSHA's standard. As indicated by CAG's acknowledgement that its risk estimate may be off by several orders of magnitude, risk estimates are necessarily imprecise because of the large number of variables (such as exposure levels, non-occupational exposures, etc.) for which accurate information is not available. Nonetheless, it is encouraging that the two different attempts to conservatively address these issues compared here have reached results so similar.

STEVEN H. LAMM

EXHIBIT A

(1) $[1.0 \text{ to } 2.5] \times 10^{-5}$ = $[10 \text{ to } 25] \times 10^{-6}$

= CAG estimate of lifetime risk of lifetime, continuous exposure to 1 ppb of benzene

(2) $\frac{[10 \text{ to } 25] \times 10^{-6}}{70}$ = $[0.14 \text{ to } 0.36] \times 10^{-6}$

= $140 \text{ to } 360 \times 10^{-9}$

= lifetime risk for 1 year, continuous (24 hour) exposure to 1 ppb

(3) $\frac{[140 \text{ to } 360] \times 10^{-9}}{70}$ = $[2.0 \text{ to } 5.1] \times 10^{-9}$

= *annual* risk for 1 year, continuous (24 hour) exposure to 1 ppb

(4) $\frac{[2.0 \text{ to } 5.1] \times 10^{-9}}{3}$ = $[0.7 \text{ to } 1.7] \times 10^{-9}$

= annual risk for 1 year, 8 hour daily exposure to 1 ppb

(5) $\frac{240}{365} \times [0.7 \text{ to } 1.7] \times 10^{-9}$ = $[0.45 \text{ to } 1.1] \times 10^{-9}$

= annual risk for 1 *work* year of 8 hour, workday exposure to 1 ppb

(6) $[0.45 \text{ to } 1.1] \times 10^{-9} \times 10^{3}$ = $[0.45 \text{ to } 1.1] \times 10^{-6}$

= annual risk for 1 work year of 8 hour workday exposure to 1 part per *million*

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

Nos. 78-1253, 78-1257, 78-1486, 78-1676, 78-1677, 78-1707, 78-1745, 78-1988, 78-1989, 78-2642, 78-2779, and 78-3023

OSHA No. 77-1395

* * * *

Before Coleman, Clark and Tjoflat, Circuit Judges.

JUDGMENT

These causes came on to be heard on the petitions of the American Petroleum Institute, et al., and were argued by counsel;

ON CONSIDERATION WHEREOF, It is now here ordered and adjudged by this Court that the petitions for review of an order of the American Petroleum Institute, et al., in this cause be, and the same are hereby granted; the provisions of the order reducing the airborne permissable exposure limit and the dermal contact prohibition are set aside and the remaining provisions of the standard in this cause be and the same are hereby vacated.

It is further ordered that respondents pay to petitioners the costs on appeal to be taxed by the Clerk of this Court.

October 5, 1978

Issued As Mandate:

SUPREME COURT OF THE UNITED STATES

No. 78-911

INDUSTRIAL UNION DEPARTMENT, AFL-CIO, PETITIONER

v.

AMERICAN PETROLEUM INSTITUTE, ET AL.

ORDER ALLOWING CERTIORARI. Filed February 21, 1979

The petition herein for a writ of certiorari to the United States Court of Appeals for the Fifth Circuit is granted. The case is consolidated with No. 78-1036 and a total of one hour is allotted for oral argument.

SUPREME COURT OF THE UNITED STATES

No. 78-1036

RAY MARSHALL, SECRETARY OF LABOR, PETITIONER

v.

AMERICAN PETROLEUM INSTITUTE, ET AL.

ORDER ALLOWING CERTIORARI. Filed February 21, 1979

The petition herein for a writ of certiorari to the United States Court of Appeals for the Fifth Circuit is granted. The case is consolidated with No. 78-911 and a total of one hour is allotted for oral argument.

[The following testimony is from the reporter's transcript of the rulemaking hearing on the proposed benzene standard]

* * * *

[859] MR. JACOBSON: Thank you. One other question here and that is the employes that were cited here had considerable dermal exposure as well as exposure in the working atmosphere as far as inhalation. Does anyone on the panel have any feeling as to whether this dermal exposure is a contributing factor or [860] is the addressing of the dermal problems with benzene in this proposed standard for problems other than leukemia.

DR. DOUGLAS SMITH: I can start it off and then if someone wants to continue it a little bit, they can. Yes, the problem of dermal absorption is, I think, real. Benzene in relation to other aromatic materials, by comparing it let's say to toluene and xylene. Apparently it is not absorbed through the skin at the same rate as toluene and xylene but it nonetheless can be absorbed.

Even if you take and have a situation in which you have got an inflamed skin or some abnormal situation, or if you have got it contained in a mixture, I believe that a considerable amount can be absorbed. I believe that this has been demonstrated in the past with measurements of urinary phenol from dermal absorption of benzene.

We don't consider that it is absorbed as a clear compound extensively. It can be.

MR. BAIER: Maybe Blair or Bob would want to discuss it from a medical standpoint.

DR. LAIGO: Well, it can be absorbed through the skin, it is readily absorbed through the skin. To what extent it would be absorbed in any particular exposure, you don't really know. You can't measure that. It certainly is a significant thing and if people are getting it on their skin, it certainly could be significant.

* * * *

[2104] MR. WARREN: Dr. Zachauser?

DR. ZACHAUSER: I am Richard Zachauser, Professor of Political Economy at Harvard University. My

fellow witnesses have testified on the adequacy and in adequacy of the Arthur D. Little report. I will not focus on that for two reasons: [2105] First, I think that the Arthur D. Little Company, assuming that it was at all responsive to its assigned task, was given the wrong task. Second, I don't think that the findings of the Arthur D. Little study, whatever they might reasonably have been, would likely have influenced the final decisions that OSHA would make. This suggests that we are in an unfortunate position where analysis is not employed to affect decision making, but might be thought of more as a charade.

Let me discuss the way an economist looks at this problem, indeed, at any problem. The science of economics is basically devoted to a very simple problem. How should we allocate resources to competing objectives. With this problem there are two objectives: One is to have economic resources available to accomplish other purposes. The second one is to promote human health.

The economic resources that are involved here are quite substantial accepting on face value the Arthur D. Little report. We are talking about $267 million worth of capital costs, $124 million worth of first year operating costs, $76 million of continuing operating costs. At any reasonable rate of discount, this is a $1 billion decision. It would be reasonable to ask, under the circumstances, what are we accomplishing? What are we buying for our $1 billion expenditure or rather, what are the people who are being forced to spend their money buying for their $1 billion expenditure.

[2106] We have a little bit of information in the Arthur D. Little report. For example, we know that there are 30,000 who are at risk levels above one part per million. We do not know, however, what happens to these 30 thousand workers. We know they are to be moved below a standard, but we don't know whether we are getting rid of 20 cases of leukemia, 10 cases of leukemia, one case of leukemia, the expected value of .001 cases of leukemia. I think that information is obviously vital to our decision making process.

The objection might be raised that we do not want to put a price tag on human lives. OSHA has continually

maintained that there is no legitimate procedure for putting a price tag on human lives and I wouldn't disagree with that. I would say that we want full information so that people in authority in the decision making process will be able to see what trade off they are making.

Basically to adopt the notion that we don't have to quantify the health benefits. Not just saying that there are health benefits, however small. There was testimony earlier that they might be non existent. To say what the actual health benefits are, I think, is essential and to argue the contrary is to say that ignorance is better than knowledge. I think that is not a very sensible thing to do.

Is there anything that we can do where we don't want to put a price tag on human lives? I think the answer is [2107] yes we can try to follow what economists refer to as a cost-effectiveness approach. Basically, for whatever resource dollars we are going to spend for promoting health, we try to achieve the maximum level of benefits. In order to do this, you have to know what benefits are going to come out of that type of expenditure.

All the time we are incurring risks because we think we get other benefits. We let people drive cars even though we know that if we put the speed limit down 20 miles per hour, we would have fewer accidents. At zero miles per hour, we would have no accidents. We allow people to eat rich desserts, live in wooden houses instead of brick houses which would be safer and I would say in all of these areas the level of risk, even if you make the most exagerated estimate of the leukemic affect of the exposure to benzene and other health consequences are much greater than the ones we are confronting here today.

I say also that the government in its regulatory processes is getting into this problem in a very major way. I was reading the Washington Post this morning and there was an article on what is called CAT scanners, computer assisted tomography which is a sophisticated diagnostic technique that assists in various medical procedures. The Federal government is presently getting into the position of regulating the use of these scanners

not that it doesn't help in an occasional instance to diagnose a very difficult disease, but the benefits in terms of improved diagnosis and medical treatment aren't worth the cost.

[2108] Here we know what the costs are, or at least we know one estimate of costs. We have no notion of what the benefits are. I should say, by the way, that other areas of government have followed the approach of putting a price tag on human lives. For example, the National Highway Traffic Safety Administration which is responsible for such things as tire standards or air bags, uses a figure of $250,000 per life safed.. I would say that if you figure the $1 billion cost per 30,000 workers, that is $30,000 per worker. That would mean that if we are being consistent with NHTSA, we would have to save one out of every eight workers.

I don't think that anybody would argue that one out of every eight workers who is presently above the one part per million standard is going to suffer from leukemia, much less die of it.

Consumers Union, which is a consumer oriented protection group, uses a figure of $1 million. Various other studies have cited numbers ranging from $150,000 to perhaps $3 million. I think it is critical that we recognize that trade off's are being made here and that we have to at least have the information as to what types of benefits one part per million offers us.

Let me get to my point about it not mattering what Arthur D. Little found. Let's assume that all the costs of the Arthur D. Little study were multiplied by three. This becomes a $3 billion rather than a $1 billion expenditure. Would any de- [2109] cision, would any of the evidence presented today, vary in any way. Take another hypothetical. Let us assume that the previous witnesses had been able to quantify exactly how many lives would have been saved. Then they corrected their testimony and they said no, we are off by a factor of 10. Only one tenth as many people would be affected as we originally said. Is there anything that is part of this decision making procedure that would reflect that change in evidence?

I think that the answer is no. Unfortunately we haven't acquired the evidence so that we could even test that particular hypothesis. I would like to make one further point about how one should treat costs here. All of the costs in the Arthur D. Little report and indeed in virtually all of the OSHA standards that I have read about, deal with average costs. They say how much will it cost us to move from ten parts per million to one part per million.

They don't ask the question about the benefits, but what we should like to know is not only how much does it cost us to move from 10 to one but how much does it cost us to move from 10 to two. We could always set the standard at two parts per million. We don't have to deal with rounder numbers. Then we could see whether the further reduction to one part per million was worthwhile.

For example, if 20 cases of leukemia per year would be saved by this particular standard, then the cost of saving one [2110] life would be $50 million. Let's assume, though, that we could save 19 of those cases for half of the expenditures by moving to two parts per million. Then that last life is costing us ten times as much. I think that the point that should be recognized is that when ADL or OSHA, when ADL conducts a study or when OSHA formulates and promulgates a standard, some attention should be marginal benefits and costs to further reductions seems absolutely essential.

I would like to pose one disagreement I did have with OSHA in general and its treatment of economic costs which is that generally they only count when they get above a threshold. This is surprising for an agency that doesn't accept thresholds going in the opposite direction to say that only if something is above five percent or only if an industry is closed down, in which case the real resources spent are, as Professor Henderson and Dr. Scarbrough testified, are underestimated. Should we count this as economic costs that conceivably should affect our decision?

So let me summarize very briefly what I say in my testimony. First, the proposed permanent standard: It

is not clear that any principal was used to set the standard. One part per million is just as good as two parts per million or three parts per million. There is an available technology methodology widely accepted in economics, widely accepted in the health care area, which is cost-effectiveness where we attempt to achieve [2111] maximum benefits per dollar expenditure.

Second, no attempt was made to determine marginal benefits. What will you gain if you tighten or lossen control? Third, no attempt was made to measure benefits. We get the same conclusion that I suggested earlier. Do we have much greater benefits or much lower benefits? Within the standard itself, there is little attempt to direct resources to where they would do the most good. It is noteworthy that this standard, one-third of the operating costs during the first year are directed to medical survailance, one third are directed to monitoring of conditions and one third are directed to reducing the risks.

Well, do we have the appropriate information as to what gains we get out of either one of these different areas? If we did, then we could use even $1 million worth of resources to achieve substantially more health benefits both within the benzene related industries and in other industries.

I guess what I would recommend for action is to understand that we do not have the appropriate information that would enable OSHA to adopt, to reject, or to modify its standards. What is needed now are analyses to compute the total benefits from various levels of standards and also information which was not provided on marginal benefits and costs.

Unless we have this information, any decision taken by OSHA now must reflect an emotional or political response to an uncharted situation where the information isn't available. [2112] I would hope that intelligent and well informed decision making should be given a chance. Thank you.

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[2141] MR. LE SOURD:

Let me turn to Dr. Zeckhauser's testimony if I may. Do I understand, Dr. Zeckhauser, that you are advocat-

ing the use of the techniques of the discipline called policy analysis and specifically that the application of cost effectiveness analysis in the formulation of occupational health standards? I am correct?

DR. ZECKHAUSER: I would say it is more than policy analysis. It is basically the way most effective government decisions are made and are sometimes put under that head. It is part of economics. It is part of government decision making.

MR. LE SOURD: You are recommending cost effectiveness?

DR. ZECKHAUSER: Yes, I am.

MR. LE SOURD: Yes. Further, are you recommending that no action be taken to promulgate such a standard as this proposal?

DR. ZECKHAUSER: I wouldn't make that recommendation. The reason being all that I have learned from reading the Arthur D. Little report and I have not reviewed the medical evidence. I have heard a little bit of it. I have discussed it with people at API and with their legal counsel. All we know is the cost of [2142] this information. It is $1 billion. We know nothing about the benefits of this information. That strikes me as making a decision in ignorance. I think we should get some notion of what the effectiveness will be before we decide to make a decision of this sort. So my answer would be yes. We have no basis to make any possible decision.

However, there are some improvements we could make even if we had to make a decision. I tried to be cost effective within the standard. Looked to see which expenditures seemed most wasteful. But I would prefer to get the basic information as to what level of protection, if any, would be afforded.

MR. LE SOURD: Is cost effectiveness always of the applicable principal for use in regulatory action of this sort?

DR. ZECKHAUSER: In protective regulation, it is frequently very useful. There are some times where a government regulatory agency may feel that it can put a price on a level of protection that is afforded. Otherwise it might chose to value a life.

I generally don't think that that is very helpful. OSHA has objected violently to it and has therefore stopped its analysis more or less burrying its head in the sand.

Cost effectiveness analysis just gives you a way of utilizing information to see, for example, that here maybe we are saving a life at a cost of $50 million where as we are failing to save lives, for example with the CAT scanner that I [2143] mentioned earlier, that would cost $500,000. We put more of our resources into CAT scanners which has been identified as a rather wasteful technology by the government and less into protecting workers in this way possibly offering very minimal benefit, then we would be using cost effective analysis to do that determination. The basic principal is that it highlights the trade off's and allows decision makers at all levels. As you know, the President of the United States has expressed an interest in OSHA's decision making processes to learn what is being gained at what cost.

This is precisely the information, for example, that the workers in the refineries themeselves and the other establishments would use if they owned the refinery and had to make the decision, should we protect ourselves? My guess that if they did attempt to make that decision, they might decide that it was worthwhile living with a little more protective equipment. As you know, that is a very cost effective way of protecting people, but as you know that is also ruled out by traditional OSHA procedures.

I think that quantifying the effectiveness and the costs of various types of impositions would immediately inform decision makers within OSHA, within the government and within the nation as a whole as to what is being gained at what cost and would enable OSHA to rationalize its interventions getting more occupational safety and health for whatever level of re- [2144] sources that are spent.

* * * *

[2149] MR. LESOURD: Dr. Zeckhauser, you have said that the guiding principle of cost effective analysis is that for whatever level of resource expenditure we are undertaking we should attempt the maximum possible

level of effectiveness. Is this a correct definition, then, of cost effectiveness analysis?

DR. ZECKHAUSER: That is part of it. The other part of it is that ultimately the decision maker should look at cost and effectiveness and decide what level of resources we want to spend. But, yes, that is an important component, and we want to get maximum effectiveness for whatever level of resources we expend.

MR. LESOURD: Would you agree that it is OSHA's obligation to provide insofar as can be accomplished a safe and healthful workplace for workers?

DR. ZECKHAUSER: As I remember the original enabling legislation, it was insofar as possible. Also, in the original legislation there was the term feasible, which has generally been interpreted to include technologically feasible. I think that any decision maker concerned for the total resources of our nation—and this is the lesson of economics that you shouldn't forget anything when you make your decision— [2150] would want to interpret that as being economically feasible as well. We shouldn't buy miniscule protection for an extra-ordinarily high amount. The problem with saying safe and healthful is how safe is safe? At what level? Why one part per million? Why not .001 parts per million Why not zero parts per million and put the petroleum industry maybe out of business if we got an absolute zero because there is no way you can assure nothing will creep through any mode of protection?

So the problem with saying safe and healthful by itself, without qualification, is that there is no level that is safe and healthful. OSHA has run into this problem with regard to a number of its standards in that they haven't been able to define that level. We had a standard of ten parts per million. If that was safe and healthful, then it is still safe and healthful. It is not as though the biology has changed at all. That was a decision we chose to make at that time on the basis of not very good information. We now it seems do not have much more good information, and we are just changing our standard.

I would like to have the information available so we could provide insofar as seems feasible and desirable a safe and healthful workplace, not meaning eliminating all risks or we would close down all of American industry.

MR. LESOURD: Did I understand then that you are [2151] equating cost effectiveness with economic feasibility? That is how you define economically feasible?

DR. ZECKHAUSER: Economic feasibility would mean that it was decided by the decision makers that the benefits were worth the cost, the marginal benefits. When we pushed it further, the marginal benefits were worth the cost. Or you may say I might refer to that as economic feasibility, yes.

MR. LESOURD: Are you saying then that in the case of this proposal for benzene that the cost effectiveness of moving from 10 ppm to 1 ppm is not sufficient to justify this change? I am not sure that I followed you.

DR. ZECKHAUSER: No, what I would say is no information has been provided so that we could compute the cost effectivenesss. We have the cost. Let us accept, subject to lowest limitations, the Arthur D. Little report as an accurate reflection of costs. Then, we would have to know—you said it yourself and you are an economist as am I—economists look at all the outputs of a process. Let us look at the costs that we are incurring. Let us look at the benefits we are receiveing. There is no discussion of the benefits. We don't know how many workers are getting protection, if any. All we know is we are moving from 10 parts per million to 1 part per million.

I would like to know how many cases of leukemia are [2152] we reducing? What other types of illness are being avoided by moving from 10 parts per million to 1 part per million? And there is no information to that effect. If we had that information, I think that a lot of this debate would go away. We are arguing in a vacuum. We know what the costs are. It is a remarkable proceeding. We know what the costs are. The argument is made that the costs aren't excessive and therefore we should have the standard. And nobody has even bothered to say, "But what are we getting for it?"

I can't say whether it is cost ineffective because nobody has bothered to tell me what the benefits are in terms of reduced healthfulness.

MR. LESOURD: Would you think that there is a difference in dealing with carcinogens versus dealing with non-carcinogenic toxic materials as to the decision that would be made?

DR. ZECKHAUSER: I think that you would want to worry about the health loss. I am as worried about workers being run over by forklift trucks as I am by workers dying of cancer. I am as worried about workers dying of heart attacks as I am by workers dying of cancer. There are losts of other diseases. Black lung disease—it bothers me tremendously. I don't like to see it, and I am delighted that we have a regulatory effort that protects miners. That is not carcinogenic.

[2153] MR. LESOURD: How difficult do you think that it would be to get an adequate dose-response function or health benefit function that would answer this question?

DR. ZECKHAUSER: I am not a doctor, but I think that the testimony earlier today, the testimony that we have been presented, put a clear upper bound on the level of benefits that could be secured. Otherwise, the debate that was going on before we came on to testify was is there any, is it equivalent to one cigarette per year, one cigarette in a life time, whatever else it might be? I think that if somebody came in and said in the most pessimistic view of the carcinogenic effects of benzene this moving from 10 parts per million to 1 part per million will save 200 lives over the next ten years and the most optimistic view of the carcinogenic effects of benzene, otherwise that it is not very carcinogenic, it will save 30 lives. Then we would know. We are saving between 30 and 200 lives, and we would say are there other ways that society can spend resources, be it air bags or mine safety or other modes of safety in the oil refinery or within the coke oven plant that will offer more health benefits for the cost?

I think we also could look for cost effectiveness even within this present standard. For example, I noticed that

there were four medical inspections per year for all sorts of different classes of workers, including some whose exposure [2154] levels were very low. That can't be cost effective. Now, it may be that we should have four for this class of workers and one per year for this class of workers unless some statistical evidence tells us that we should increase that level of surveillance. But there is no attempt to do this. It is sort of the notion of you provide absolute protection with absolute standards. As a consequence, cost effectiveness is left out of the discussion. Effectiveness is left out of the discussion. Benefits are left out of the discussion. Health is left out of the discussion except that health is at risk, and that is sufficient to set a standard.

* * * *

[2156] MR. LESOURD: You are saying then really, if I understand you, that the relative risk and probably other matters such as latency period and the dose-response function have to be known before you can make these calculations of cost effectiveness?

DR. ZEKCHAUSER: I think that we should make some [2157] effort to gather the information that we have, to collect that information before we make a decision. Yes, I would say that is the case. We can put upper bounds. The discussion this afternoon suggested that we can put upper bounds on the dose-response relationship. You may argue that it is here, and I might argue that it is here. But even if we accepted your estimate the most tangential studies we would have an upper bound of what it might be. And I think that information should be part of the standard setting process.

MR. LESOURD: On page 8 of your written testimony you stated that OSHA "should make every attempt to be consistent across the broad sweep of problems encompassed by occupational health and safety." By consistency do you mean the trade-off rates, which I believe was your term?

DR. ZECKHAUSER: Yes. If that were done, then we could be sure that the total level of impositions of OSHA we would be getting the maximum health benefits. So that if OSHA is, for example, with its cotton

dust standard, a very great health problem, sacrificing lives at $500,000, otherwise for an additional $500,000 a life could be saved, but with benzene saving a life at $50 million, then what we should do is cut our expenditures in benzene. And with that same $50 million we could save I guess—I can't remember my numbers exactly, but I think it is 1,000 workers in the cotton dust area.

[2158] MR. LESOURD: But aren't you—

DR. ZECKHAUSER: I don't remember what the numbers are—

MR. LESOURD: Isn't it true that the expenditures that the textile industry may make for compliance with the regulation are not transferrable to some other industry for them to expend. So, you are not really comparing anything.

DR. ZECKHAUSER: But to the extent that most of these expenditures are borne ultimately by consumers and taxpayers at large. The textile industry raises its prices. The benzene industry, petroleum industry, petrochemical industry raises its prices. We bear the cost particularly if demand is inelastic. So, too, if the companies lose profits half those profits are absorbed by the taxpayer at large so that an awful lot of the costs go back to, you know, John Q. Public. So, I think from that standpoint the costs are transferrable.

But I am only saying within the broad sweep. I don't mean that it has to be one to one. But let us not have it 1,000 to one. Of course, here we don't know what it is at all because we have no notion as to what that ratio is, although we can put a minimum on it.

MR. LESOURD: Then, you are not really saying that they should be equal?

DR. ZECKHAUSER: In an ideal world maybe you would [2159] have them equal. It is sufficient we are so far from the optimum that it would be good to move in the right direction. We could dramatically improve occupational health and safety, save resources at the same time, if we had a ratio where one was 100 to 1 and one was 1 to 1 by moving so that one was 30 to 1 and one was 15 to 1. As to whether they should move finally to

equality that is sort of a refinement that we can get to later.

MR. LESOURD: How far do you think that OSHA should go in comparing standards? Should it look at the total range of all possible health and safety standards and then examine the trade-off among all of these before it acts on one?

DR. ZECKHAUSER: No, I don't think it should. I think they should come up with standards as they are identified and as they come to the public view. I think if we gather the appropriate information and fed it into hearings such as this one and in its promulgation of regulations it was made available in the newspapers and to Congressmen, to the press, and the President, then very shortly there would be forces pushing towards equalization. But, I think that we should protect workers against benzene now. The question is to what level should we do that? We don't have to worry as to what we are going to be doing with cotton dust tomorrow or five years from today. But we can look to other areas. NHTSA, which I mentioned earlier, this Traffic Safety Agency, [2160] is already proposing a lot of standards that are already in effect. We can use that as a vague guideline.

We can look at OSHA's other standards as a vague guideline in terms of what we would do now. But the main thing is that if we had the information then people would comment. Congressmen would say this is outrageous. No, we didn't want to spend this amount of money. When we passed the OSHA Act, we didn't understand what was really involved. Many Congressmen are saying that.

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[2167] MR. LESOURD: Am I correct that you seem to be assuming that you know the benefits, yet you are telling us that the trouble is we don't know the benefits? Yet you are saying that the benefits of this change from 10 to 1 can't justify the costs? It seems to me that you are doing that.

DR. ZECKHAUSER: I don't think I am being clear, and I apologize. We know from earlier testimony. They were quarreling this afternoon as to what the maximum

benefits could be. We can get a maximum estimate of the benefits, and then we could say it is worthwhile. What is the most number of workers that could be protected? I think that we could provide some guess in that direction now. Maybe I am wrong. If I am wrong, that information should have been generated.

I would like to use that information to decide what we do right now. But I would also like to refine those estimates, get estimates of marginal benefits, get not the extreme valuation of the benefits but something more in the middle of the range so we can know what sensible action should [2168] be taken. So, I don't claim that we have the knowledge of the benefits.

My guess is, though, that medical witnesses would give some maximum level. I think that is what they were doing this afternoon.

MR. LESOURD: You do feel, do you, that even if all that we could ever know was what some upper bound might be on these benefits, there would still be a basis for action at some time at least when we had determined that that was all we could know?

DR. ZEKCHAUSER: Well, I don't think that we will ever determine that is all we can know. There have been many other areas where we started off with a broad guess. Eventually we refined it. I don't think that would be too hard to do. I think that it is quite possible in this case that knowing the maximum benefit might tell us what we shouldn't do. It might tell us that this present decision is wrong. It might not tell us exactly where we should set the standard, whether we should lower it as far as 5 parts per million. It might not tell us whether we should have four medical inspections per year or two medical inspections per year.

For example, in medical inspections I think we will know within one year what sort of benefits come out of four inspections per year as opposed to one inspection per year. We might run a controlled experiment. It would be very easy [2169] to do. That is not something where we have to have new insights into epidemiology. We can say, look, with these 1,000 workers we gave them four examinations per year and we didn't find anything,

with these workers we found an awful lot. You know an awful lot more about the benefits of those medical exams. I think that we could find out that information.

So, I think that the first question we should ask is, "Without our present estimates of maximum benefits and our estimates of costs, however good or bad they may be, does it seem worthwhile just to move from 10 parts per million to 1 part per million?" I think that is a question that we can ask.

And that information is not provided, and that information is not generally part of OSHA's decision making.

* * * *

[2180] DR. PARTRIDGE: Fine, given the time frame available for a variety of analyses that might be undertaken, if we were to take the approach that you are suggesting to look at a variety of potential regulations, what would we do in an interim situation where we have a potential or a known carcinogen that requires regulation?

DR. ZECKHAUSER: We would collect information on the costs. That is what your organization has done.

[2181] DR. PARTRIDGE: Correct.

DR. ZECKHAUSER: We would collect information on the benefits. There is some information that is not presented. It was not presented in your report. I take it that was not the charge to Arthur D. Little. It is normally not a charge that OSHA makes. We would provide that information, and we would make our decision on the basis of the best information that we could gather. Here we have not provided the best information that we could gather.

I would like to see in your report or in the document that promulgates OSHA standards a notion of using this piece of epidemiological evidence we estimated that these benefits would be provided, using this piece of epidemiological evidence which is much more optimistic or pessimistic or whatever else it is these would be the benefits that would be provided. This was the range that came out of the studies that we examined. That is what I would like to do. In the interim if that information were provided, I would like to compare it across

other areas. At least I would like to have it provided so that OSHA for its own internal decision making purposes would use it in a reasonable fashion.

DR. PARTRIDGE: Okay. In this type of situation then would we be able to draw upon preceding studies as a basis for future promulgation, where we are gradually [2182] accumulating a body of literature and knowledge, be it cost effectiveness or what have you.

DR. ZECKHAUSER: You certainly would, but we couldn't in the occupational health area given OSHA's refusal to quantify the benefits from its impositions. We would have to look at this time to studies done in other areas with the hope that since OSHA has been a playing an increasing strong role in the occupational health area that soon we will have broad enough studies that would be able to inform us.

DR. PARTRIDGE: Begging the issue of whether or not OSHA is willing to quantify benefits or not, would you be prepared to utilize information that is now being collected as a basis for quantifying the value of human life for a variety of regulations?

DR. ZECKHAUSER: Well, there is a difference between quantifying the benefits in terms of how many lives are saved and quantifying the value of a human life. I think that quantifying the value of a human life so turns off large groups of people that it is not something that should be done. It doesn't inform the decision making process very much, and it just gets people upset. Now I have actually seen some Arthur D. Little studies that did do that, and I think they had precisely that effect—the Pan American Health Organization worrying about the benefits of mosquito eradication.

[2188] DR. PARTRIDGE: Fine. On page 13 you make a statement more significant the uncertanties usually the greater are the benefits for some sustained study of the problem. If initial predictions of health benefits range, say, over true orders of magnitude, several months of investigation may narrow the prediction to within a factor of 10. Extremely narrowing of this sort may dramatically change both the form and severity of

the regulatory intervention that we wish to employ in a particular case.

Would you briefly describe to my what types of additional investigation you are advocating here?

DR. ZECKHAUSER: Well, what I would do is I think I suggested earlier I would start off by asking our medical witnesses to attempt to quantify the benefits, and obviously we have got a range, with some people suggesting that benzene causes more cases of leukemia than others. I think that we would be most able to narrow uncertanties in something like the frequencies of monitoring and surveillance, medical surveillance, where I think a good control study within one year could tell us an extraordinary amount, whether 50,000 exposed workers will pick up—and nobody would know right now —200 disturbing symptoms, sets of disturbing symptoms or two. You gain an awful lot knowing that, and right now if somebody were asked to testify they would have an extra-ordinarily broad range. There is a study. We could do it, [2189] do it in a year, and we would have a much better standard in a year from today.

[2190] DR. PARTRIDGE: You are talking about an almost after the fact evaluation of certain compliance activities. I prefer to go back to perhaps issues of toxicology and—

DR. ZECKHAUSER: I repeat my opinion with regard to benzene. I don't know what the level of uncertainty is over the leukogenic consequences of benzene exposure. I heard some discussion as to whether 10 parts per million was safe or one part per million was safe, and I guess we could find out something more about that. I would like to see those studies conducted. It might take some time. At the outset since I don't think that it would matter much for the standards, and certainly not the way they are implemented, I would even be willing to live with a reasonable maximum estimate of the benefits, and make that information available to Congress.

DR. PARTRIDGE: Have you participated in any of these studies that you are advocating, these additional studies? Are you aware of any such activities and the results of such an activity?

DR. ZECKHAUSER: I haven't done them in terms of occupational health and safety. I have done them however in other areas. For example, I participated in a study that was published this spring on the risks, costs, and benefits of surgery and when we started that study we didn't know whether various surgical procedures were very effective or efficacious.

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[2459] MR. VAN VOORHEES: Your Honor, first we have Dr. Howard Maibach appearing on behalf of the American Petroleum Institute.

JUDGE LAWRENCE: Present your testimony.

DR. MAIBACH: My comments will be very succinct and limited to one simple issue, and that simple issue is how much, if any benzene, applied to the skin of man goes through the skin. In order to make some sense of the recorded data that is present to you in the literature, to anybody, I have taken the liberty of summarizing it into two parts, with interpretations of each.

The first part starts in 1897, and the second part starts in 1946. The first part in 1897 were attempts [2460] to determine how much benzene goes through your or my skin by applying the material to animals. Now, in 1897 when this was done, there was essentially no information available as to how the skin of a guinea pig or a rabbit differed from our skin other than the fact that we obviously share some dissimilarities in appearance.

The first observation was by Santeson in 1897. The material was applied to the rabbits. The rabbits had had their hair removed, and the skin of the rabbit changed under observation, and they questioned whether the material went through it.

The next observation was in 1925 when Morrow applied material to guinea pigs. The guinea pigs had their hair removed. Again, there were no quantitative estimates to determine how much went through, just to see if there was a change in the physical appearance of the skin.

For all practical purposes then, the first observation to try to determine how much benzene goes through the

skin was in 1931 when Lazarev and his associates did a simple experiment in which they immersed either the ear or the paw of rabbits or mice into benzene for some hours, and then they attempted to measure how much, if any, of the material went through the skin by looking for benzene in the breath with a colorimetric assay, and they came up with a figure, which has been [2461] published and quoted, stating that the amount of penetration was several milligrams per centimeter per hour.

I think that it is very likely that for the rabbit this is probably a very correct observation. The problems with extrapilating that to your skin or my skin is simply that the amount of benzene used was enough to "mummify" the skin, which is a very different situation than you or I working with benzene. Mainly they were dealing with very abnormal skin.

Next Leeman attempted to measure the penetration of benzene through the skin of animals and records that he saw no penetration.

The last animal experiment was by Petrilli in which benzene was applied to the skin of the guinea pig in a pack, and I will get into the significance of a pack, and "slight intoxication" was noted.

I think the most relevant experiments are those that started right after World War II in Italy, leaving the skin of animals and going directly to the skin of man, and the reason that I believe that this is relevant is that we now know that there are very grave differences and very important differences with man being superior to the animal.

If one wants to give it a teleological connotation, mainly that man has a skin that is able to [2462] keep chemicals out a great deal more effectively than many animal species, and certainly much more effectively than the rabbit.

The first experiment after World War II in man was done in 1946 by Cesaro. He did a rather heroic experiment, by many standards. He took some men who were volunteers, he removed their clothing and placed them in a tank. He then, in the tank, gave them a breathing apparatus so that their skin could be exposed. He meas-

ured the amount of penetration of benzene by using a technique of comparing the ratio of inorganic sulfates to total sulfates. Now this is a relatively crude method in 1977, and using that technique and applying the benzene both as a vapor and a liquid, and he doesn't explain how much he applied, he found that there was no penetration.

The next experiment was done by the people known as the Research Association of British Rubber Manufacturers. They took a somewhat different tack. Instead of just applying vapors they applied liquid benzene to the chests of the volunteers, and they examined both the sulfate ratios, the total sulfates, and they looked for benzene in expired air, and they too came to the conclusion that with their experimental technique and with the analytic techniques available in 1947, that they found no evidence of penetration.

[2463] We now go another few years. We go to 1956 when Konka and Maltigliotti did an immersion experiment. Here they took the hands of workers, immersed them, their hands and their forearms, in full strength benzene for 25 to 35 minutes. Again, they used as their analytic method the evaluation of breath, and they used the sulfate ratio method, and they too, again, came to the conclusion that under the circumstances of their experimental technique, in immersing the hands, they found no evidence of penetration.

The last experiment and the one that is the most important, because here a postive result is equally as important as a negative result, Hanke and his associates in 1961 did a somewhat different experiment. In 1961 they took some benzene, and unfortunately I have had to read this in translation because I don't read Czech and I have read the official translation provided to me, but what they did was they applied the benzene in cotton pads and then they applied a plate over the cotton pads. Using this, and using another technique for measuring penetration now, or as an index of penetration, namely the amount of phenol appearing in urine, they came to the conclusion that there was penetration of benzene in the subjects that they studied.

Now this experiment has two problems of [2464] interpretation. The first problem is that they were not measuring the penetration of benzene, they were measuring the amount of phenol, and the people that they were studying already had a fair bit of phenol in their urine, so one is stuck with the problem of trying to extrapolate how much of the phenol was present in these people before they started out, and how much was due to that added from the benzene.

The additional problem of interpretation here is very simply that Hanke, in 1961, didn't know that any time you take a piece of anything and you cover the skin with it and you wrap it with an impermeable dressing, such as the glass plate, you greatly alter the permeability characteristics of skin, and for those chemicals that we have data on, which is unfortunately not benzene, we know that it is one of the most potent methods of driving molecules to the skin.

You may know that dimethylsulfoxide is written up in many of the lay journals and scientific journals as an extremely efficient way of driving molecules into the skin. Well, dimethylsulfoxide is not nearly as efficient at driving molecules into the skin as that little piece of plastic or a piece of glass. So, the data that Hanke observed has the one problem of interpretation, how much of the phenol was due to the benzene, how much was due [2465] to natural phenol from other metabolic pathways and secondly, how does one extrapilate by his plate be applied over the cotton to the situation of the worker.

I would like to summarize both the animal and the human data by saying that in 1977 it is extremely difficult, if not impossible, to balance all of the information that is available. Admittedly, the overwhelming majority of the observations suggest that benzene does not penetrate the skin. One observation suggests that it does.

Today we have a much simpler and a much more direct way of answering this, and I would hope as the result of the deliberations of this congregation of observers and official party that in a very short period of time we could get a very specific answer because now radioactive benzene is available, and one simply would

apply radioactive benzene, some Carbon 14 benzene, to the skin of the arm of an appropriate animal that has permeability characteristics similar to the people in this room, and the monkey and the guinea pig, nor the rat would fit into that category, and then would simply look for the radioactivity excreted into the urine the feces and the breath.

This is a simple technique. It has been done for over 100 organic compounds in the last decade, measuring the amount of transport to the skin, and it would then tell us definitively, without argument, and efficiently, [2466] just how much of any benzene penetrates the skin.

Using the simple technique, it then would become possible to answer a number of other very relevant questions for people like yourselves responsible for making standards.

Question number one, is the material absorbed from the palms the way it is from the forearm or from the chest because there is a greater difference between the absorption of one part of your body to another than there is in all of the people in this room.

For instance, for some of the chemicals that have been measured, there is a 40-fold difference between one anatomical site and the other in man, and so I think if we are talking about standards for benzene, the site of the workers skin that is exposed certainly is a site that should be studied.

Secondly, a very critical problem that must be answered, in all of the data that has been provided to me, it is assumed that benzene applied to the skin has the same or equal toxic potential compared to benzene inhaled which is believed to be the major point of entry.

Well, I think in the 1940's this was a very reasonable assumption to make. In the 1970's, we are aware of a number of examples where the skin metabolizes compounds in an entirely different fashion than any other part of the body, and references are in my written testimony. So, [2467] therefore, once you start to do this and use modern analytic techniques, it should be possible to determine is the skin detoxifying or is the skin handling this in

a way similar to the lung, or is it handling it in a different way.

Next, we didn't know, until 1977 a very basic part of this story. In 1976 we believed that if you splashed a chemical on your skin once, or if you splashed a chemical on your skin ten times, we assumed that if you applied once and IX went to the skin, if you splashed it on ten times then 10X went through the skin. We now know, at least for one chemical, it is the only chemical that has been measured, that that, although it is a basic assumption of all dermatologic therapy, happens not to be correct, and the data for this is in my written testimony for the one compound.

So, in setting standards for benzene for workers, one would also want to know is there a difference in one exposure versus multiple exposures, and again, with modern analytic and biological technology, it should be very simple, very quickly, and inexpensively to answer this.

Another practical matter to be resolved is can one in fact protect you or myself or any worker with protective clothing. It is automatically ordinarily assumed that this is in fact the case, but until you do an [2468] experiment with the protective clothing, using appropriate methodology, one cannot make that assumption. It is very possible that you may be, but it is equally possible that it may not be, and it is something that can be demonstrated.

The last two things that one could measure very effectively today, within a period, I would think, of 12 weeks, and that is is the amount of benzene that is absorbed through our skin concentration dependent. Certainly, in broad range, it must be concentration dependent, but in the practical matter of setting standards, we do not know whether there is a linear relationship for all chemicals in terms of the amount of absorption.

Then lastly the thing that would be extremely germane to know in setting standards is that benzene is a very volatile material. When it is splashed onto the skin, is it going to evaporate more rapidly into the air or is it going to go into the skin more rapidly. I think all of these and several other questions could be very expeditously

answered if any of the appropriate agencies who are interested in setting the standard wish to obtain the data.

JUDGE LAWRENCE: Thank you very much, Dr. Maibach. Does the Solicitor have any questions?

MS. KALARIS: Yes, we have just a few questions. Dr. Maibach, you said that the evidence was not clear as to [2469] whether or not benzene is absorbed through the skin. What is your personal view?

DR. MAIBACH: Well, I appreciate a direct question, and I will give you an equally direct answer. I don't know.

MS. KALARIS: Thank you.

DR. MAIBACH: May I clarify you, because I think it is important to be in the record.

MS. KALARIS: Certainly.

DR. MAIBACH: I think it should be emphasized through normal skin of man rather than skin of rabbit. I think we must separate those.

MS. KALARIS: Would the rate of absorption of benzene be greater through the broken or the damaged skin than through the intact skin?

DR. MAIBACH: It is ordinarily assumed that penetration of any molecule will be greater through damaged skin than undamaged skin, but unfortunately I have to tell you that today that is usually as assumption rather than a fact, namely in many dermatologic situations where we are trying to drive molecules through the skin for therapeutic purposes, we have almost no background data to verify that assumption, and it could be that when we get the data, it may be very surprising.

MS. KALARIS: What is the basis for the [2470] assumption?

DR. MAIBACH: The basis for the assumption is that your skin is protected by an outermost barrier, the dead skin, the stuff that you see in the bath tub interferring with the soap, on the side of the tub, the carotene or stratum corneum. That barrier, that little dead layer of cells in fact is a perfect membrane for allowing you and I to get out of the seas. Namely, this is the membrane that keeps water in us.

It has been assumed, and it is certainly true, that if you remove that membrane, if you damage it, the water comes right out of you. It has been assumed, in fact, that it does the same thing for chemicals. Well, the little bit of analytic data that we have done suggests that when we move that barrier we only increase penetration for the few chemicals, and I don't want to generalize on this, about three-fold, and I told you that a little piece of Saran Wrap will increase penetration about 10-fold.

Stripping off this barrier increases penetration about as much as dimethylsulfoxide would, not as much as occlusion, and certainly there seems—whoever created us gave us other barriers to penetration, other barriers to protect us for chemicals going in, other than just the stratum corneum.

MS. KALARIS: Then liquid benzene could damage [2471] that barrier?

DR. MAIBACH: Liquid benzene could damage that barrier.

MS. KALARIS: Once the skin is broken, would multiple applications produce more penetration than a single application?

DR. MAIBACH: Last year I would have given the answer yes. This year, on the basis of the one reference of new data that I have given you, I don't know.

MS.KALARIS: And your answer would apply whether or not there was just splashing of the skin or there was drenching?

DR. MAIBACH: Would you kindly repeat that?

MS. KALARIS: You said you don't know, and this year you said you do not know the effect of a multiple application, and that would be the case whether or not there was just splashing, the application was by splashing, by intermittent contact with the skin, and would also be the case if the skin was thoroughly drenched?

DR. MAIBACH: I would still say that I think that experimental data must be obtained, because it is very practical information.

MS. KALARIS: Is there any data which shows that repeated skin contact does not result in absorption?

DR. MAIBACH: The only data that is available—
[2472] MR. VAN VOORHEES: Is that with benzene?
MS. KALARIS: With benzene, yes. Of course.
DR. MAIBACH: No, I don't have that data.
MS. KALARIS: Okay. Is benzene absorbed more readily if it is in another solvent such as to toluene or xylene, does it penetrate the skin more readily?
DR. MAIBACH: I found no data for or against that. Again, very easily measured in 1977.
MS. KALARIS: You mentioned a 40-fold increase in certain anatomical regions for some chemicals. What part of the body were you referring to?
DR. MAIBACH: Well, I was specifically referring to the scrotum. Every chemical that we have studied to date, using radio isotopes, and using man, suggests that the scrotum has essentially no barrier to penetration for many chemicals.

For instance, the first one that we studied was hydrocortisone. Hydrocortisone is very poorly absorbed, very minimally absorbed in the forearm. About 40 percent of the dose is absorbed in the scrotum.

Some of the pesticides that we have applied, 100 percent of the dose is absorbed in the scrotum.
MS. KALARIS: So other parts of the body would be less sensitive?
DR. MAIBACH: Generally speaking, we know of [2473] no area other than the scrotum that is completely permeable. I might add that the female genitalia have not been studied so we don't know the answer.
MS. KALARIS: You mentioned Saran Wrap increasing absorption from three-fold to ten-fold. If you are wearing a shirt, for example, would that shirt, if it is splashed or drenched with benzene, act as a Saran Wrap and increase the absorption?
DR. MAIBACH: The only data that we have bearing on this is with totally inclusive materials.
MS. KALARIS: Such as?
DR. MAIBACH: Such as plastics, rather than shirting. Shirting would be an entirely different—it would be a very relevant question to ask, but we have no background data to date.
MS. KALARIS: Thank you.

JUDGE LAWRENCE: Do we have any questions from the floor? Mr. Alexander?
MR. ALEXANDER: Thank you, Your Honor. My name is Victor Alexander, I am here on behalf of the Industrial Union Department of the AFL-CIO.
JUDGE LAWRENCE: Would you estimate your time?
MR. ALEXANDER: I will try to keep it within a half an hour, Your Honor.

Dr. Maibach, is there some standard way that [2474] experimenters use to apply an occlusive dressing? Can you describe that to us, in an animal experiment?

For instance, if you apply a piece of plastic or Saran Wrap, are the edges sealed?
DR. MAIBACH: Could you clarify a little bit? If I knew what you were driving at, I might be able to answer that.
MR. ALEXANDER: On page five of your statement, you say it is not clear whether the watch glass was used as an occlusive dressing, and I am just trying to get out if the fact that it was held down by an elastic which might have left the edges open for evaporation, if that would qualify as a standard type of occlusive dressing, as you understand it.
DR. MAIBACH: I don't have any ready answer for that.
MR. ALEXANDER: On page six of your statement, five and six, at the bottom, and then going over, you talk about them having performed 52 tests for the concentration of phenol, and that they found an average of 7.2 milligrams of phenol per liter of urine, and that this was the baseline observation.

Further down the page you say that the maximum concentration observed in the controls was 16 milligrams. Do you have any idea how those data were distributed? For [2475] instance, how many of them had values, say, above ten?
DR. MAIBACH: I don't really have a specific idea. I can give you the exact data.
MR. ALEXANDER: Good.
DR. MAIBACH: In translation.

MR. ALEXANDER: I don't read Czech either.

DR. MAIBACH: Here we are. This is page 10 of their Table Two, and it is entitled, "Maximum Values of Phenol Excretion in Urine in Unexposed Persons, and Persons Who Absorb Liquid Benzene Through the Skin", and the maximum concentration of what they call, in this particular table, "physiologic excretion", and it is 16.0 milligrams. One of their exposed subjects had 15.8.

MR. ALEXANDER: Excuse me a second Doctor, I was interested specifically in the controls.

DR. MAIBACH: Okay, they give, as the controls, 16.0, in this particular table.

MR. ALEXANDER: That was the maximum value?

DR. MAIBACH: Maximum concentration in milligrams per liter.

MR. ALEXANDER: You reported, on page six, that the average was 7.2 milligrams.

DR. MAIBACH: Okay, that could be a different table. The table that we are referring to there is their Table One, "Physiological Values of Phenol Excretion in [2476] Different Unexposed Individuals", and there were 52 tests with a result that they say test results from 3.0 to 16.0 with an average of 7.2.

MR. ALEXANDER: My question really relates to, in one case, at the top of page six here, you are referring to 7.2 as a baseline, and further on in your comparisons, you use 16 which is the maximum observed value for controls, and I ask you if it really wouldn't be more appropriate to consider 7.2 the baseline rather than 16.

DR. MAIBACH: It is a very germane question. I chose to use what the authors chose in their discussions.

MR. ALEXANDER: If, in fact, one were to do that, then the five values you report for the exposed subjects would then have concentrations of phenol in the urine on the order of two to three times as much as what I might call the baseline.

DR. MAIBACH: For that reason, I think if you and I were doing this, in light of standard experimental design, neither one of us would do it this way, would we? We would take each person as his own control because you would have to worry about outlyers, and if you

notice their table in which he gives his physiological excretion of 16, 3 of the 5 subjects were at baseline level. I think 2 were above it.

MR. ALEXANDER: At the maximum level for controls [2477] when you say baseline.

DR. MAIBACH: Right. So, obviously that made him a little uncomfortable too.

MR. ALEXANDER: On page 7 you state that the authors do not appear to eliminate the possibility that these two subjects, meaning the two that are above the so-called baseline represent a contamination from another source. I wonder if we were to apply the other version of baseline, if, in fact, it might not be a question whether or not the 16 value that was observed might not have been from contamination of another source. If you might turn that phrase on it's head, so to speak.

DR. MAIBACH: It is an interesting question, I don't have a good answer for it.

MR. ALEXANDER: You have written several papers about using a standard technique, which apparently you developed for studying both pesticides and other organic compounds. Is that correct?

DR. MAIBACH: Yes.

MR. ALEXANDER: If I can refer to one paper in particular, which is called "Absorption of Organic Compounds Through Skin in Man", it contains several interesting things, one of which, on this question of recovery in urine, after IV administration, two compounds which have some reasonable similarity to benzene, that is [2478] dinitrochloro benzene, and nitro benzene, those would be benzene compounds with some substitutions. In those cases, something on the order of 60 percent was recovered in the urine, and do I take it to mean that if a similar situation occurred with respect to measuring phenol, that we might be talking about an actual absorbed dose, something on the order of twice as much as they were actually measuring?

DR. MAIBACH: Yes, that is a very easy question to answer. If you measure—if I put some benzene on my—if I put some melathion on my forehead, and if I accounted for one percent of that being excreted in the

urine and stools, there could still be a very significant underestimate.

If I didn't know what happened when you put melathion into the body to be sure that in fact you could find it in the urine and stool, so we therefore correct or incomplete excretion after foreheadal dose.

MR. ALEXANDER: I wonder next what the effect of worker sweating would be on the absorption of a compound. Is it likely to be increased?

DR. MAIBACH: Unfortunately we only have one objective documented study on this work we did with a pesticide. It was either parathion or melathion, and it is unpublished work, but I can provide the experimental data. We found surprisingly no difference with the one [2479] pesticide we studied and one anatomical site, in one statistically significant experiment. The statistical significance was we could show no difference.

MR. ALEXANDER: That is a little bit surprising?

DR. MAIBACH: Like many things in membrane transport, once you get the data, it is often very surprising.

MR. ALEXANDER: Based on that, do you have any idea what the mechanism for the increased transport, when you are using an occlusive dressing would be?

DR. MAIBACH: We have pat answers that we give to students who are not very questioning. Do you want those or do you want the real answer which is I am not sure that we know?

MR. ALEXANDER: I wonder if some of the experiments that are described were conducted at 25 degrees Centigrade. I wonder if, for instance, in a working environment where the temperature might be 40 degrees, if that might have an effect to increase the transport.

DR. MAIBACH: If I understand your question, it is two parts. One, does the occlusion—

MR. ALEXANDER: No, I am not talking about occlusion. I am speaking about temperature.

DR. MAIBACH: There is every reason to believe on the basis of invitro studies, that increasing [2480] temperature will increase penetration, but again, as in all of these things, that is going to have to be documented with in vivo studies.

MR. ALEXANDER: How about the humidity? The experiments described discuss 35 percent humidity. It is relatively common to find an environment where the humidity might be 70 percent or higher. What would that do to the rate of transport?

DR. MAIBACH: I think that is going to have to be measured in vivo before I will be comfortable enough to answer.

MR. ALEXANDER: Now most of these experiments relate to compounds applied to the forearm skin, and in some of your published work, for instance, you say that skin, such as the angle of the jaw or the face would have a, based on the experiments that have been done, transport factor some four times greater. Is that correct?

DR. MAIBACH: The chemicals that we have studied, it is the general rule that the face is more permeable than the forearm.

MR. ALEXANDER: And the back of the hand, compared to the forearm, is perhaps twice as great?

DR. MAIBACH: We have very little data on that, unfortunately.

MR. ALEXANDER: In one of your papers also, you [2481] site an individual variation from person to person of five times in the amount of a compound. I think it was specifically pesticides absorbed. Do you have any reason to suspect that same sort of variation might not apply to the case of benzene?

DR. MAIBACH: I think we need the simple experiment to answer that.

MR. ALEXANDER: You also talk about—I understand the caution you are giving us about whether one dose or multiple doses, but you mention, again, in your paper, something about the effect that it is possible to have sort of an overwhelming dose in which there may be a linear relationship of absorption to concentration to a certain point, and then much more of the compound would be absorbed.

In the case, say, of a mechanic, who opens a pipe and is inadvertently soaked in the stuff, might not that be a case where you have this overwhelming event?

DR. MAIBACH: I don't recall having made a statement about overwhelming absorption. I wonder if you could clarify that for me.

MR. ALEXANDER: No, I didn't mean overwhelming absorption, I meant that there seems to be a relatively linear relationship between concentration and absorption up to a certain point, and then after that, more compound [2482] applied, a greater proportion of it might go through the skin.

DR. MAIBACH: Okay, I understand now.

MR. ALEXANDER: I was just trying to give a practical application of this concept.

DR. MAIBACH: There are purported examples in which the opposite occurs, namely at very high concentrations one gets less absorption than one gets at lower amounts, and I think you would have to obtain the data to know what would happen with benzene.

MR. ALEXANDER: Now, as I understand it, your standard protocol is to do a complete urine collection for five days, and you report for several different compounds, the pesticides for instance, half lives ranging from up to 28 to 30 some odd hours. Now, as I understand it, the standard practice would be to collect urine for at least three half lives to be certain of a reasonable collection over 90 percent, and based on that, since in the experiments you report, there seems to be an incomplete urine collection for a period of 24 hours, if in fact that might not be a significant understatement or the total absorbed dose.

DR. MAIBACH: One can plot that out mathematically, and we do, and in fact, on certain compounds, we have collected as long as 20 days. Hexochlorophene is one [2483] of them because of it's slow, half life in excretion.

MR. ALEXANDER: Also, if I understand some of your work correctly, you also speak about the fact that various layers of the skin can act sort of as depots, storage depots for the compound, and that this may explain some of this delayed absorption, but in fact, the compound may be stored in one or another of the layers, only to be released very slowly later on. Is that a fair representation of—

DR. MAIBACH: As a general rule, I would not know if that would hold with something like benzene.

MR. ALEXANDER: I guess I just have a couple more questions then. Again, in that paper that I was referring to earlier, you mention on page 400 that three compounds, possibly two toxic to test intraveneously in man or administered instead intraperitoneally in guinea pigs.

I wonder if you could tell us why you chose not to administer those compounds to man. The compounds, I believe, if I am reading correctly are butter yellow, malathion, and methylcholanthrene.

DR. MAIBACH: Butter yellow we chose not to apply, and I am thinking back a decade, and I would have to look at my notes.

MR. ALEXANDER: I appreciate that.

[2484] DR. MAIBACH: Butter yellow is a low grade carcinogen. Methylcholanthrene is the same, for the same reason. Malathion has, we subsequently realized, to be very easily administered to me intravenously,—

MR. ALEXANDER: So your concern with two of those compounds, at least, was the possibility of their having some carcinogenic risk.

DR. MAIBACH: Yes.

MR. ALEXANDER: Now, on page 11, your last comment is that similar studies could be safely done in man because the chemical and radiologic exposures are extremely small.

I wonder if based on this prior work of yours, and if in fact benzene has a carcinogenic risk, whether or not you might be concerned about conducting an experiment of that sort.

DR. MAIBACH: Well, at the time we wrote this, we were unaware of the fact that there is a very good animal model now for this, and so I would be very happy to run it as an animal model.

Secondly, we have learned a great deal more general toxicology than we knew then, and would feel very comfortable about injecting tracer quantities into myself for instance.

MR. ALEXANDER: The final question is, I [2485] understand that these experiments are done on human

volunteers, and I wonder whether the protocol for such a study has been submitted and approved by the human experimentation—

DR. MAIBACH: For benzene?

MR. ALEXANDER: Of your medical school.

MR. MAIBACH: These experiments have, but not for benzene. We have suggested in this that studies like this should certainly be done for benzene, either in an appropriate animal model, which would be the one of the species, monkeys, that we have correlated data with other compounds from animal to man, or certain—I suspect that this would probably clear many committees for the use because of the very small doses needed because of the exquisiteness of the analytic methodology available today.

MR. ALEXANDER: Thank you, Doctor. Thank you, Your Honor.

JUDGE LAWRENCE: Do we have any further questions from the floor? Mr. Wodka?

MR. WODKA: Five minutes, Your Honor. Dr. Maibach, the National Institute for Occupational Safety and Health has placed into the record here a 1972 German study by Hartwich. Are you familiar with that one?

DR. MAIBACH: May I take a look at it please?

MR. WODKA: Sure. Well, let me read to you [2486] this part of it. I don't have the entire study. I have a reference to it. What they did was this, they found an increased incidence of structural chromosomal aberrations in a group of nine refinery workers who did not have clinical hematological or biochemical abnormalities.

The concentrations of benzene measured in the individual outdoor working areas had at no time exceeded 25 parts per million. However, there had been prolonged skin contact with benzene with all the workers, and I would like to know if you think this observation is significant?

DR. MAIBACH: I am afraid that I am not familiar with that paper and would have to study it before I would comment.

MR. WODKA: Let me just show you this. This is the —one of the NIOSH references that was "Considera-

tions Bearing on the Question of Safe Concentrations of Benzene in the Work Environment", the MAK-WERT paper.

DR. MAIBACH: Thank you.

MR. WODKA: I have just excerpted some of the—

DR. MAIBACH: I would be very happy to step outside and read it and return after I have studied it, but I have not studied it before.

MR. WODKA: I just have one other question. [2487] I have listened here to your oral presentation, and I have noticed that in several places you stated that more work is needed in order to explore the question of skin absorption of benzene, and I think you expressed several places where more research is needed, more tests need to be done, and so on.

Don't you think, therefore, that it would be prudent for workers who are exposed to liquid benzene to wear gloves, impervious gloves, during this period of time while we don't have all the data?

DR. MAIBACH: That is a very direct question and the face of it is so simplistic is to be silly, and I don't think you meant it that way. Obviously, it makes a great deal of sense to protect all of us from all of the risks of the world, and I, like motherhood, must endorse it. However, I think the specific question that I am addressing myself to here is that whoever makes these standards does have a lot of practical issues to deal with, and this is one practical issue which is perhaps the most straightforward, namely how much of this material goes through skin, it could be answered before this committee's deliberations are finished. We are talking of a relatively short term experiment. In six to twelve weeks, one could have an enormous amount of data that could allow one to make some reasonable judgements without having to resort to the [2488] motherhood type of principle.

MR. WODKA: Well, I understand that, and I saw that in your testimony, but my question is if I, as a Union representative, came to you and said that I had a group of workers exposed to liquid benzene, and I was going to ask you, in your expert opinion, do you think

it would be prudent for me, as a Union representative, to insure that these workers wear impervious gloves when they handle up the benzene, what would you tell me?

DR. MAIBACH: I would tell you what I have been told by the people, the Union people who speak to me, and the workers who speak to me, and the State agencies that speak to me, namely that you must preserve your warnings with both you and me, whether it is smoking or anything else, to the most relevant warnings, and so I am saying that in the six weeks necessary to do these experiments, you will have your answer.

I don't think it is particularly effective to make a generic warning for everything, because then I think everything is disregarded.

MR. WODKA: So, in essence then, you would want to conduct your experiments first before you give me an answer?

DR. MAIBACH: I would like to, again, remove the first person from that answer, saying that I would be [2489] for you or anybody in this room who is interested in doing it, the techniques are straightforward and reliable, and it could be done by anybody having the analytic facilities available.

MR. WODKA: Thank you.

JUDGE LAWRENCE: Anybody have any further—

MR. WODKA: Do you want to hold on to that?

JUDGE LAWRENCE: Do you want to answer that question?

DR. MAIBACH: Would you like me to then write you or go out in the hall?

MR. WODKA: You could write me.

DR. MAIBACH: Okay. Fine.

JUDGE LAWRENCE: Do we have any further questions from the floor?

MS. KALARIS: Dr. Maibach, would you submit your opinion on that article for the record please?

DR. MAIBACH: Yes, I certainly will.

JUDGE LAWRENCE: Mr. VanVoorhees, do you have any questions?

MR. VAN VORHEES: I have just one question, Dr. Maibach. If an employee were wearing impermeable

clothing or gloves, and in the process of handling benzene, liquid benzene got underneath the gloves, would that increase the absorption potential of the benzene?

[2490] DR. MAIBACH: If benzene is like other chemicals that have been studied, and that must be demonstrated, the occlusiveness of the glove would be a very potent way of increasing penetration.

MR. VAN VOORHEES: I have no further questions.

JUDGE LAWRENCE: Thank you. Thank you very much, Dr. Maibach. Mr. MacDonald, do you want to be second?

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[2701] DR. WILSON: The corrections I have to make are mostly typographical. On page 18 of my testimony on line three the word "most" is typed and it should have been "worst". It is "under the worst case".

On page 24—

MS. KALARIS: Would you go a little bit slower, please?

[2702] DR. WILSON: Page 18 there is a typo and line three. It should be, "suggests that benzene is at worst a weak mutagen," not "at most".

MS. KALARIS: Yes.

DR. WILSON: On page 24, in the various tables, in all of these tables, that should read, for example, on page 24, it should read on the first number, it should be 10 to the power of minus 6. The minus 6 is put on the same line as the 10 in all of these typings and it should be read as a superscript.

On page 25, the third entry in the table, it is incorrectly typed. It should read five times 10^{-4}.

On page 29, line nine, there is a correction because here I was referring to the draft study, the Arthur D. Little, which was done for OSHA, and the final study has slightly different numbers in it. So that I will have to correct these statements here.

On line nine it said "Calculated in the above OSHA study," it is $75 million for 12 months plus $250 million capital cost, which, if I amortize at 10 percent, corrected for inflation, it gives a total of $100 million a year.

Then I would go on, "Corresponding to a cost of $300 million for every hypothetical life saved". Those are the corrections, the ones that I found.

[2703] I will give you a brief summary and try and put this in the framework that has already been mentioned. I would like to—well, I want to point out in my testimony what I believe is a necessity of making a risk estimate in any situation involving either the workplace or an environment, whether it is a carcinogen or not.

It seems to me that anyone who claims that benzene is a leukemogen or a carcinogen must put numbers into a statement and preferably numbers into the dose so that that automatically will give him some estimate of a risk no matter how rough it is and peoples' reluctance to make this estimate is, in some senses, to my mind, synonymous with a reluctance to believe that benzene is in fact a carcinogen.

Likewise, I believe that it should not make much difference to OSHA action whether benzene is found to be a carcinogen or not or merely a suspected carcinogen. OSHA, in its regulations, should be careful if it is a suspected carcinogen and should put reasonable limits on the dosage.

If it is found to be a carcinogen, there is no reason, in my view, and I can't see anything in the law either, that there should be a sudden switch in what it does and even though the emergency standard, the proposed emergency standard, in the preamble, said something about [2704] having to reduce to zero emissions, I believe that is not reasonable and one should make a risk estimate in both cases in order to properly protect the worker and if one insists on too low a risk, then one is not protecting other workers enough because one may be spending too much on protecting that one group and without any benefit to that group.

Now, the dominant feature, it seems to me, in the emergency standard as promulgated and as I have heard just a little bit of the questioning is the failure of OSHA to put numbers into a risk and to state what relation this proposed standard has to public health and particularly to health of the workers.

Without such a relation I don't quite see how one can usefully make a new standard.

Also, I want to emphasize that there seems to be no emergency involved here. We have been using benzene for 50 years. Indeed, we were using it at those levels far higher than we are now using it. There have been no dramatic cases of leukemia that have been standing out all over the place and in fact, as the evidence has shown, it is hard to prove that the cases of leukemia that have been seen are indeed attributable to benzene.

Therefore, a short delay, while we try and understand the situation, should not have catastrophic [2705] significance. This is not a new chemical and it should not be treated as such.

An emphasis has been placed on a simple yes or no on whether it is carcinogenic or not. This by itself I believe is nonsense, particularly in today's framework. 30 years ago when you had three carcinogens, radiation, cigarette smoking, and beta-naphthalamene, I think.

Now we have about 150 known human carcinogens and 1,000 animal carcinogens and if we were able to look with human beings with the sensitivity we can look in animal experiments, most of these animal carcinogens would, I think, be found to be human carcinogens.

Yet, the laws of science haven't changed. These things haven't suddenly become carcinogens. They were carcinogens before. That is just what they are now.

I suspect that if we improve our techniques we will find more suspected animal carcinogens and we have to be careful about that.

We can put them on a scale now and in fact table C of my testimony I put such a testimony which came from a paper of Mr. Meselson and I put some limits of benzene on that scale. We will see that at a worst it is a very weak carcinogen compared with the strong ones that we know how to deal with. We have examples. It is also a weak mutagen.

[2706] On a direct carcinogen, which we have heard about, mutagenesis, carcinogenesis, are usually related, and that was the point, of course, of Meselson's paper. Benzene is at least 100,000 times weaker than aflatoxin

as a carcinogen. Aflatoxin we regularly eat with the peanuts offered on American Airlines and Allegany Airlines and so on, and even available in the FDA cafeteria.

It is also a thousand times weaker than benzoapyrine which we regularly pour at our workplace and environments and kitchens and fossil fuel burning, from our cars and from charcoal burning foods.

Even if benzene is found to be a carcinogen in the end, at the level of the limits I took, I believe that OSHA should tackle the bigger hazard first. If indeed it is correct that OSHA wants to have a policy of stopping all carcinogens, they should stop smoking in the workplace, particularly all hearing rooms, OSHA cafeterias, and anywhere where people work.

They should also stop people working anywhere within a quarter of a mile of a car so that we don't have—which can be done. It is quite feasible. Maybe we should wear gas masks. I worked several days with a gas mask in the second world war as an air raid warden. Fortunately only in practice.

It is possible for us all to wear gas masks in [2707] the cities and it is feasible and that might be the technical meaning of the Act.

However, I think the right thing to do is to evaluate the risk, see if the risk is sensible. It is indeed, as I can testify. Wearing a gas mask does reduce one's availability to do work. I have done it in order to show that I could carry out my duties as an air raid warden while still wearing a gas mask. It was possible but a lot harder.

Moreover, you know, we can measure these substances and control them better than ever before. 30 years ago if we found a substance that was found to be carcinogenic it was not only potent but it was present in high concentrations.

The sort of policy that OSHA seems to be talking about today might have made sense 30 years ago. Nowadays we are finding weak carcinogens. We are finding them in low concentrations. To make an absolute statement, it is a carcinogen or not and making a change in rules in accordance is to my mind wrong.

So that we have to do—now early in the hearing Professor Zeckhauser testified and he quite correctly rejected putting a value on human life and his way of talking about cost effectiveness analysis. In my testimony I gave an example of how on a reasonable basis, pessimistic [2708] basis, on how benzene might be a carcinogen, this proposed standard, using the Arthur D. Little study, will cost about $300 million for every hypothetical life saved.

Spending that $300 million is not done without a waste of life. We know that every time you build a building lives are spent, about one for every $20 million spent in construction. Now, that $300 million won't all be in construction but a rough estimate suggests that the $300 million, three other lives will be lost. So for saving one hypothetical one we will have spent three. I believe that is not correct.

Now, the question therefore is we have to have a yardstick in order to compare risks and benefits. The public interest lobbying organization called The Federation of American Scientists in a study of carcinogenesis a year ago called for such a yardstick.

The Federal Register on May the 22nd last year, Russell Train, Director of EPA, said one should compare risks and benefits and said that is what they were supposed to do and mentioned it was the new change in policy. I hope they follow it.

It has been said—so, I think that is what OSHA should be trying to do in the hearing and unfortunately, it didn't come in the preamble to the proposed statement. The risk analysis that I try and present and the comparison [2709] with other testimony are rough ones because, as we have heard, the data on possible carcinogenesis is rather rough.

However, I think it is about the best one knows how to do.

So on the—if we take this conservative hypothesis one would then come to a feeling, I would come to a feeling, that although there may be some, a more careful study might show it in some places, one could reduce this standard below 10 parts per million without this huge expenditure which is in the Arthur D. Little report.

Incidentally, I would point out that is not an industry report. It is an OSHA-commissioned report. One would normally expect industry to be more pessimistic about how much it costs and an OSHA-commissioned report to be more optimistic. But this is the OSHA one.

So, in the Arthur D. Little report they do mention something in the latest copy about the possible benefits of this. But only in extremely rough terms. They make no estimate about making a risk study, no attempt to compare these risks with any other risks in society so as to give one perspective, and so that I believe this is a major defect in that Arthur D. Little study and in that I completely agree with Dr. Zeckhauser that these defects, although omissions in the Arthur D. Little study, are so [2710] great that some of the details which he and other people were also concerned about in that study are comparatively irrelevant.

I want to make one more comment. The Arthur D. Little study comments that the OSHA policy is that putting dollar costs on risks is arbitrary. I would certainly agree it is somewhat arbitrary. It is, however, done, as Dr. Zeckhauser commented in his testimony and I would just add on one more place where it has been suggested, and that is in the Nuclear Regulatory Commission hearings, the so-called "as low as practicable hearings" which lasted a period of two to three years and was finally ruled on last year where they suggested $1,000 for a man-rem of exposure which has a possible level below which one should reduce radiation exposure.

They reached this by taking the most conservative number that anyone had suggested to them and rounding it on upwards to be as safe as possible. If you take the same linear projection on cancer incidence that I took in my study, this corresponds to a number roughly of $10 million every hypothetical life saved and that is somewhat less than $300 million which I estimate that this proposed OSHA standard would take, according to the Arthur D. Little study.

So that I believe, in fact, that such numbers have [2711] been done in the Government, should be done again, in fact, should be done very much more than they have been in the past.

JUDGE LAWRENCE: Thank you, Dr. Wilson. Off the record.

(Off the record discussion.)

MS. KALARIS: I would like to advise everybody that we have in the back copies of page four, page five, page eight and page 10 of Professor Wilson's presentation.

JUDGE LAWRENCE: Page 30.

MS. KALARIS: Oh, that is page 30 of Professor Wilson's statement. Those pages were missing from some of the copies obtained through the Technical Data Center. So if you need them, they are out there in the back.

JUDGE LAWRENCE: All right, any further business? All right, there being nothing further, the hearing stands adjourned and we will resume tomorrow morning at 8:30 a.m. Thank you very much.

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[2721] MS. KALARIS: Would you explain please what you mean by a weak carcinogen?

DR. WILSON: Yes. If we look at my Figure 3 in my testimony, this comes from the work of a colleague of mine, Matthew Meselson at Harvard University. Now he was very much impressed, as a lot of people have been, that in a very large number of carcinogens, which were found to be animal carcinogens, there is a direct proportional relationship between the ability of this chemical to produce revertance in a mutagenic test of the type of Bruce Ames at the University of California. The relationship between if you do a study on animals where you do a lifetime study of feeding of this particular carcinogen, and this graph is taking to those cases where a lifetime study is available on animals, and there is also a mutagenic study available.

It is quite significant in my mind that over a range of approximately 10,000, some chemicals produce more [2722] mutation activities than others by a factor of 10 to 100,000. Those same chemicals that are more potent in producing mutations are also more potent in producing cancer.

For example, on this curve the most potent one on the curve, I am not sure it is the most potent carcinogen we have—I don't think so, is aflatoxin B_1. That is in very small quantities it is known to produce cancer in animals. Two parts per billion will cause according to the NIT of that study by Jerry Wogan, will give 10 percent of the rats cancer. Whereas if you do similar tests, for example, on benzopyrene, whereas a test here is on Chinese hamsters, you would find you would have to have a 30 to 40 times the concentration of the chemical to get the same number of rats dying. If you do the same test on saccharine, you will up the curve at the top right hand corner, you will have to have a dose of 7½ percent of saccharine in the diet, fed continuously, in order to produce 15 percent cancers.

So there is a very wide range, well over 100,000 into the factor between the potency of some carcinogens and others. These are, I would like to note, what one might call direct carcinogens.

If benzene is a direct carcinogen, I put on this graph where it might lie because if it is a direct carcinogen, it would presumably show up on an Ames Test. It hasn't [2723] according to the information I have from the people in Bruce Ames' lab. It has been tested, and they haven't found anything. They haven't found anything, I don't accept a yes or no as an answer to this sort of question.

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[2732] MS. KALARIS: How do you define an insignificant risk, Dr. Wilson?

DR. WILSON: Oh, the only way of regarding a risk as insignificant, in my view, is very much a personal question, and it has to be by comparison with others. That is why I have always, in my own mind, I have not been content with calculating risks of anything until I have compared it with something else. Something else particularly without getting involved with personally if possible and something else which I can calculate on as nearly as similar basis as possible. Then if one risk is very much smaller than the other, say it was less than 10 percent, then I would tend to regard it as insignificant.

MS. KALARIS: On Table I you have calculated risks for certain occurrences.

DR. WILSON: Table I? Yes, there it is.

MS. KALARIS: All right. What relevancy does that sampling of risks have to the risk of developing leukemia from occupational exposure to benzene?

[2733] DR. WILSON: That has less relevancy than some of the later tables, but it—incidentally I have just realized there is a misprint on line 2 of that, my division can't possibly be correct. Excuse me, I have line 2 with a risk from falls of 17,000 people must be 9 times 10^{-5} and not 9 times 10^{-10}. I must beg your pardon because it is clearly the total number divided by.

The relevancy, to go back to the relevancy question, these are risks which various elements are exposed to it in various ways. Some are exposed to some and some are exposed to the other. I personally try to avoid the risk of firearms, I am never able to avoid the motor vehicles or the falls or the fires or the eletrocution for example. Those are risks to which we are all exposed to in life. Now I would normally, the two aspects of which this is a risk we ought to expose to whether we work on a subject or not. If benzene work on an ordinary person, you would have that risk.

Now risk of benzene is a risk in the working place. A risk that is usually accepted, and I would think it reasonable to continue, that if a limited number of people in a limited occupation can be exposed to slightly higher risk due to that occupation, than the general public. There are a wide number of cases; otherwise without that you would clearly have the obvious cases, climbing a scaffold, [2734] fix a building. That is clearly a very risky thing to do. You clearly stop the general public from doing it, you don't let them get up there. But you nonetheless ask a worker to do it. So that is not directly applicable to worker, but it is so that should in general those risks that you would expect you would allow a worker have a sightly larger risk than those ones that he is generally exposed to in that sense.

But those are just to give a perspective and nothing much else.

MS. KALARIS: Thank you.

(Pause)

MS. KALARIS: Isn't the significance of a risk relative? For example, in your written testimony, you cite the example of no one reasonably worrying about being killed in a hurricane. Now this might be true in the United States, but it may not be true in another country where hurricanes are an annual hazard. So isn't it a question of selection of priorities?

DR. WILSON: Oh, absolutely. Risk is certainly right to question. Of course, there are numbers on hurricanes in the United States which is also very important to note that although a hurricane is widely defined to be an act of God and of course in that sense it is. Nonetheless you can protect against it and reduce your risk, and a [2735] cautious person would look, in fact it is quite notable the people who calculate risks in this business of calculating risks, calculating them will in fact start avoiding hurricanes and choosing their airlines rather carefully and so on.

MS. KALARIS: Would you agree, then, if one's prime objective is to protect as many workers as possible, one may not be willing to accept a risk which entails a few workers being exposed to a hazard?

DR. WILSON: I am sorry, I don't understand the question.

MS. KALARIS: We said that, if I understood you correctly, you agreed that risks are relative.

DR. WILSON: Correct.

MS. KALARIS: Ok. If one's primary objective is to protect as many workers as possible from a particular risk, one may not be willing to accept the risk which entails few workers being exposed to the hazard. In that case doesn't the risk become a significant risk rather than an insignificant one?

DR. WILSON: I am still not quite sure to understand it but let me try to answer and see if I have got it correctly.

There is a prime objective for protecting human life, that is correct. In the framework of this hearing, [2736]

one can talk about that limit that particular groups of people who are working people. Now indeed risk is a variable question and as I said, it is somewhat an individual question. It is important not only to make sure that the risk to all of society be small, but there is no individual group in society which is unfairly being called upon to shoulder a very large section of the risks. I believe that that is perhaps what you were trying at in that question. I would agree with that that you should not ask one limited section of people to take unusually large risks merely for the benefit of the rest of society without some concomitant benefit for these people or giving them perhaps the opportunity of rejecting that particular option of accepting that risk.

I will give an example. We all know that being an astronaut is a very risky business. Quite apart from the risk of the thing failing and exposed to cosmic rays and radiation at a level far exceeding the ordinary industrial level. Approximately one trip to the moon is 20 times the yearly dose for an occupational worker. The astronaut is asked to shoulder that risk. They shoulder it willingly; they would have an opportunity declining. Although they are exposed to a larger share of risk than anyone of the general population, I don't think it is unreasonable.

MS. KALARIS: On Tables III & IV, would you turn to [2737] those please? You state that on the basis of these tables, occupational exposure to benzene presents an insignificant risk. Are the risks calculated for these tables all hypothetical risks?

DR. WILSON: No, they are not. Some of them are real. Some of them are known. Let's see.

MS. KALARIS: What —

DR. WILSON: —Some of them are rather certain, and the ones on benzene are hypothetical and may be overstated.

MS. KALARIS: Ok. What did you hypothesize? Or what assumptions did you make in calculating the risk of benzene?

DR. WILSON: Oh, I went back. That is back on several pages back. That is a fairly normal, if I may go through the assumptions I made.

Starting with Figure 4, my Figure 4, I tried to make sense out of this highly discorded set of data. As I plot the data, I put various dotted lines on it. I have tried to assume that no one was completely wrong; that no one was actually lying or anything like this, but there was some misinterpretations of some parts of the data. Mr. Aksoy, for example, he found twice the standard cancer in Turkey, 13 parts per thousand. It is possible he missed quite a few cases so one can, I didn't put it on the figure, but one [2738] might assume as Pat Faulker that twice as many cases is the dose level I thought was 200 parts per million. I believe he stated that. Faulker could clearly have missed some cases and one could go upwards on that. I was not quite sure what to make of recent NIOSH study. I had assumed as had Dr. Tabershaw gave testimony yesterday, that he was talking about these cases being 15 parts per million. I am not quite sure that he still holds to that, but we looked at it last night.

It doesn't explicitly say. Anyway, I was guessing that he had understated it, and that was more like to be 100 parts per million or even some different chemical. Because otherwise it is very hard to make sense of that data and at the same time assume that there aren't too many shoemakers left in Turkey. Vigliani's data, I assume, was slightly high.

So I took the bottom curve on this, bottom line, the risk liner 1.8 times 10^{-6} per year at one part per million dosage. That is the slope of that line. That probably what the data really is assuming a straight line instance. That is saying a straight line is pessimistic.

I could have taken one of the other lines with this discordant set of data, but I was reluctant to admit that everyone in Turkey was going barefoot. Then I said I have seven other cancer case in tobacco smoking, for [2739] example, we all know that the first case we found was lung cancer. Yet that there are lots bladder cancers we now come across, perhaps twice as many cancers as the number in the final cite. So I doubled that risk and brought it up to 3.5 times 10^{-6} at one part per million.

Now, this would be risk—Oh, this risk by the way is

slightly overestimated risk, because that is by taking the ratio to the normal instance.

Now if you look at, now the one reason for taking the ratio to a normal instance is to save myself work, and to use the work that other people have done. Because when you want to calculate the normal instance, you have got to complicate age correction on what the age of the people concerned with. I didn't want to go through that work, but the people who have done these studies have done that work. By taking that ratio, you can factorize that part out.

Now, this risk then becomes correct if people were exposed to this benzene not only their working life but until they die. But in fact, they are not exposed to the benzene for age 65 to age 80, and it is quite likely therefore the risk is overstated by a fact of two. Nonetheless, I have left that stand. So that number, 3.5 times 10^{-6} per year at one part per million becomes 3.5 times 10^{-5} per year at 10 parts per million. That is I calculated that risk.

[2740] DR. WILSON: I don't know that benzene might be a direct carcinogen. If it is a co-carcinogen only, then it is wildly overstated.

MS. KALARIS: Doctor, what is the risk at 10 ppm as compared with the risk at one ppm?

DR. WILSON: According to this way of calculating, it will be 10 times as much. Incidentally, that is one of the advantages of taking a linear calculation. Everytime people plan to do risk calculations and do these general calculations; Dr. Pochin, myself, other people; we always try and assume over a wide range there is a straight line curve.

If you don't do this, the calculations become tricky. It becomes much harder to visualize them, and so on, and so although this is perhaps overstating the benzene figure, I believe if you want to do public policy on a risk calculation basis, this is a fairly prudent and slightly conservative thing to do.

MS. KALARIS: Thank you. On page 28 of this statement, you assume that 30,000 people are now exposed to three ppm benzene concentrations.

DR. WILSON: Yes, that was—

MS. KALARIS: Can you explain the basis?

DR. WILSON: Yes.

MS. KALARIS: For the level assumption?

[2741] DR. WILSON: Yes, I was taking this report, the report of Arthur D. Little for OSHA. Now, the page number I have got here, Page six, second paragraph, was from the preliminary draft of this, and I must apologize. I only got the final thing a couple of days ago, and I should have updated that page reference.

But they say in there somewhere, and it was page six, second paragraph, that the standard would effect 150,000 people, and only 30,000 of these now have concentrations above one part per million.

I tried to get out of that study a number, a sort of graph of who is exposed to what. Maybe it is in there, but I didn't find it. It is not very clear. It seems to me perhaps a weakness, it is not clear. I shouldn't be grumbling about a report not being clear because many of mine aren't either, but I couldn't find that so I made the estimate; there is clearly going to be some distribution. They won't all be at the top. So I made a very rough guess that they were three parts per million.

I believe that if you are to do this job properly, you are supposed to improve my risk estimate and go over this rather carefully and probably do a complete integration over these numbers, but I am trying here to pull in what is, I believe, a major gap in the justification [2742] OSHA had for what they are doing, what they are proposing, and outline the method by which OSHA would do it.

MS. KALARIS: On page 29, I believe you stated that only a few 100 people would be regularly exposed to 10 ppm of benzene concentration. Can you explain the basis of that statement?

DR. WILSON: That is maybe incorrect. It came out of a page in this report here, and again, they were vague on this particular question. Therefore, I am a little vague on it. Probably, as I was thinking about it last night, I think a few hundreds; it is probably closer to 1,000 than 100, but I really don't know.

* * * *

[2753] DR. LLOYD: Dr. Wilson, on page four, the paragraph on the [2754] page, you say, "I wish to make it clear that, of course, we did testify. I satisfied myself that benefits should be included. The manufacturing of benzene at ten parts per million level up-graded the potential risks associated therewith." I would ask, benefits to whom and risks to whom?

DR. WILSON: Okay. I possibly answer that question, of course, just now. There is a point here which your question brings out, that in fact, the potential risk will be to the benzene worker. It is going to be in my view a considerable benefit to society. There is an important feature in any one of these cases, as in fact in all cases where anyone that is employed in any sort of occupation riding a bus or an aeroplane that some measure of this benefit be passed upon individual workers, and there are various ways of doing it in society.

A classic way in a really dangerous occupation, which this isn't, is giving a worker hazard pay, but this is no way near that. But this has to be born in mind.

DR. LLOYD: And then you do that since in comparison to other risks which society regards as insignificant. Would you say that that little worker is insignificant?

DR. WILSON: Pardon?

DR. LLOYD: Would you say that the death of a [2755] worker is insignificant?

DR. WILSON: The said the risks can be insignificant. I have never regarded death as insignificant. I can regard a risk as insignificant, but not a death.

DR. LLOYD: Well, then, what are you referring to when you say, "Society regards them as insignificant." What do you mean by "insignificant"?

DR. WILSON: "Insignificant" in this case is much less than other—"Insignificant" would be in this regard a risk which in most people's ordinary calculation of what to do from one day to the next, you would not take account of even if you were aware of the details of the calculation.

DR. LLOYD: Is that what we are talking about here when we are talking about workers who died from leukemia?

DR. WILSON: I am sorry. That is what I was talking about on page five. Indeed, that is why I think the main important feature is my table, Table Three and Table Four. I think Table Three is particularly important. It is particularly important, it seems to me, to make sure that society is not asking a worker in a benzene factory to shoulder a risk which is appreciably greater than risk in any other occupation.

That is the reason why I listed some of these.

* * * *

[2772] DR. LLOYD: When you said you estimated the risk of the benzene-leukemia problem, you described it as inspired guesswork.

DR. WILSON: No. I think it is—in one direction it is a guess. In the following sense: I have, we have some data. It is a lousy set of data as we have had several times during this hearing. It is data on the interpretation of which people have disagreed, and now I have made a estimate, I think it is slightly better than a guess, on what the risk might be. Now you might—it is open to other people to disagree, but the reason why I think that it is more than a guess is, for example, suppose I was to assume that the latest NIOSH study of Infante and Young and people was literally correct and was five times the normal instance at ten parts per million of benzene. [2773] And I was also to assume that there was a plot which was approximately linear and no worse than linear between effect and dose. I see no reason why it should turn over. Then it would be very hard to say why at two hundred parts per million you would not just be getting five times the normal instance, you would of course have to be getting one hundred times the normal instance. As I said before, I just don't see how there can be a shoemaker in Turkey left. And although I know, no doubt, there are some people in Turkey that go without shoes, I don't think everybody does.

And therefore, I don't believe that it is merely guesswork. It is correlated. Trying to correlate this piece of information, trying to explain—that is why somewhere in here I may have said it is very hard to take that study

completely literally. Of course, I must say that I made an error in my reading. I don't think they said that those cases were ten parts per million. There may have been some sort of implication there, that I thought there was. If there are higher figures, or in fact due to other chemicals, then that could be the explanation of that figures. It is hard to say that it turned out not to be benzene at that dose level. It might be, but that would be very much upsetting all the indications that we have got.

* * * *

[2820] MR. MACDONALD: Your Honor, we do know that Dr. Aksoy has done extensive industry research.

DR. WILSON: I knew that and I forgot that.

DR. LLOYD: You have made reference a number of times to Dr. Aksoy and to shoemakers. In reference to your statement that all of the shoemakers in Turkey should be dead on the basis of the Infante estimate—

DR. WILSON: Yes. No. Not on the Infante estimates but upon the estimates of the Infante Study if they were at 10 parts per million.

DR. LLOYD: I realize what you are saying. Now, couldn't it be that with benzene we might have a situation analogous to what we have in beryllium and with asbestos where the people who are at the very high exposures show an acute disease which is not presented as cancer as is presented in beryllium and asbestos and it turns out in the end result when we look at these patients that the people who have the long latent disease are people who got essentially lower exposures. Couldn't that be the case with benzene? Particularly in light of Dr. Aksoy's report with so many of the shoemakers dying from their blood dyscrasia.

DR. WILSON: What you are suggesting to me is that there might be really different dose-response curves for this particular case?

DR. LLOYD: Yes.

[2821] DR. WILSON: It is conceivable, I suppose, that any dose—response curve is possible. I would— It would be a rather unusual, almost I think, revolutionary contribution to the literature on cancer to have a dose-response curve on cancer.

DR. LLOYD: You agree with what I am describing is true for beryllium and for asbestos?

DR. WILSON: Well, beryllium is not a carcinogenic in this way.

DR. LLOYD: It is not a carcinogen?

DR. WILSON: Not in this way. I mean it is not a direct carcinogen. I don't know that it is direct. The people I know who had beryllium poisoning have not died from a carcinogen. It does not have the carcinogenic properties. They have mostly died of ankylinicosis which is not a carcinogen.

DR. LLOYD: Are you going to be attending the beryllium hearings?

DR. WILSON: No.

DR. LLOYD: I would suggest you do.

DR. WILSON: I haven't time to attend all hearings and still try and understand what is going on in one or two of them.

DR. LLOYD: Now in reference to insignificant [2822] risk when talking about risk as a personal guess in compared to other things and how you do this yourself relative to matters like jumping off—

DR. WILSON: That is right.

DR. LLOYD: Do you know whether in general workers exposed to benzene, or for that matter, any person, were ever given a chance to make such a conscious choice?

DR. WILSON: Yes. Some workers are. I don't know if all workers are. A person is given—certainly in the radiation field which I know a little more than in the carcinogenicist's field. A person who is employed is told that he is a radiation worker and told to carry a film badge and can deem to accept this job or you can accept it if you wish. And you can take another job, maybe in the same company.

[Exhibit 2-46 (list of references omitted in printing)]

OSHA TRANSLATION

OSHA-76-62

Med Lavoro
46:194-198, 1955

STUDY OF THE PERCUTANEOUS BENZENE ABSORPTION

By

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We believe that a study of percuteaneous benzene absorption is timely; accordingly, we performed a series of experiments in man, involving direct contact with liquid benzene, i.e., the tests were implemented under conditions which actually reproduce those forms of contact which occur during industrial use.

For a prolonged period of time—we may safely say ever since the professional study of benzene pathology started—various authors investigated the possible penetration of the toxin through the cutis surface.

The characteristics of the substance which is a powerful lipid solvent, soon led to the assumption that benzene with its significant lipolytic properties active at skin level, could break through the protective cutaneous barrier; it was suspected that the substance enters the circulation over that path and disperses in the organism.

Santesson was first to investigate the problem experimentally in 1897. His tests were performed in rabbits with the application of pure benzene pads on the shaved cutis. He reached the conclusion that benzene absorption does occur.

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[2] Later Mauro, Lazarew, Brussilowskaja, Lawrow and Lifshitz, expressed analogous opinions, always on the basis of animal experiments.

Mauro used guinea pigs, placing pure benzene packs on their cutis and leaving these in place for two hours every second day. Introducing an alternative of the Santesson method, depilation was used instead of shaving the guinea pigs so as to avoid abrasions through which benzene might penetrate.

Lazarew, Brussilowskaja, Lawrow and Lifshitz experimented with rabbits, soaking a paw in a pure benzene bath and attempting to prevent the animals from inhaling vapors originating from the bath.

In a monographic study on solvent pathology, Lehmann and Flury contested the conclusions reached by the above authors. They found instead that no cutaneous absorption could take place, nor would the absorption be of any interest in practice; they limited the question to an exclusively theoretical level.

Petrilla conducted interesting research work in laboratory animals. He tested 15 guinea pigs, in part with intact fur, in part after mechanical or chemical depilation. The animals were subjected to benzene evaporation involving the cutis of the entire body, excepting the head. The presence of intoxication symptoms was verified in almost all animals, including some guinea pigs with intact fur. The last-mentioned animals showed, after 6 days of testing, cutaneous modifications as well as macroscopic changes such as hyperemia, edemas and chapped skin lesions. The author interpreted the results by confirming the possible capacity of benzene to transgress the cutaneous barrier, even when said barrier is intact.

More recently, Nunziante Cesaro showed interest in the problem. This [3] author refers to experiments performed in man. Individuals with perfectly sound cutis were placed for a period of 20 to 30 minutes into a metal tank in which the atmosphere was saturated with benzene. The head of the test subject was kept outside through an opening in the tank; a rubber tube linked to a face mask provided inhalation of vapor-free air. The dosage of the urinary sulfate derivatives was determined

before, immediately after, one hour after and two hours after the start of the experiment.

The practically unchanged SI/ST ratio and the absence of benzene in the air led the author to the conclusion that percutaneous absorption does not take place, at least not when the cutis is perfectly intact.

Subsequent investigations resulted negative as well; they involved the application of cotton wool layers saturated with benzene on the upper limb cutis of some test subjects. The limb was kept for 20 to 30 minutes in a sealable sleeve. No benzene was recovered, not even in traces, from the exhaled air of this second test subject group.

Based on the total opinions stated in literature, the conclusion can be reached that two diametrically opposite views exist, both supported by a considerable number of authoritative researchers.

However, early experiments performed in animals are readily subject to criticism because the applied techniques either fail to guarantee the perfect integrity of cutaneous surfaces in contact with benzene, or do not strictly exclude possible inhalation of the toxin. On the other hand, under close scrutiny even research in man does not prove to be entirely convincing.

In our opinion, the principal objection against the work of these authors concerns the use of air saturated with benzene and the use of pads saturated with the solvent; these contact methods can be defined as "indirect".

[4] Said methodology can be justified by the attempt made to preserve the test subject from any morbid symptoms, including their cutaneous forms; the method nevertheless results in a questionable solution of the problem since (said method) is incomplete.

We do not believe—even from a purely theoretical viewpoint—that it is actually suitable to investigate possible percutaneous absorption of a liquid such as benzene in contact with the skin of a worker by using vapors in saturated form or by extending the contact over the entire body surface; physiologic knowledge concerning cutaneous permeability does a priori exclude any absorption in that form in case of lipo-solvents as well.

The above objection essentially also applies to the use of cotton wool saturated with benzene, placed on the cutis of a limb in a sealed sleeve. Under such conditions a transient and incomplete contact with the liquid solvent will evidently occur; but, since benzene evaporates rapidly, it will never be present in a volume sufficient for eventual absorption, and the result will merely be a vapor-saturated atmosphere in the sleeve.

For the above-mentioned reasons our research work was based on different criteria.

We selected test subjects, including a female, to evaluate the effect of individual cutaneous characteristics. The tests were performed on alternate days.

Direct contact with the toxin was accomplished by immersion in "commercial" benzene of the type used by a large factory manufacturing rubber articles. Maximal contact duration was limited to 25-35 minutes because already after a contact duration of 5 to 10 minutes from the start of testing the exposed cutis surface became intensely and increasingly painful; the [5] pain was characterized by a burning sensation.

The following technique was applied (see the photographic description of the instruments):

The subject introduces a hand and 2/3 of the forearm into a metal tank supported by a tripod; the surface of the tank has an opening fitted with a rubber sleeve and can be completely sealed; a face mask with double valve is then applied to the subject who starts to inhale, through a long rubber tube, air from the external environment. This protects against vapor inhalation during the test. Benzene is introduced in to the tank through a tube attached to a suitable container.

Towards the end of the testing period a hog bladder with an approximate capacity of 3 liters is attached to the exhalation valve of the mask; it becomes thus possible to collect an air sample and verify whether it contains any benzene vapors.

[Figure 1 omitted in printing]

We used two methods to determine the eventual percutaneous penetration [6] of benzene. With these methods, the elimination of the toxin from the organism can be controlled, i.e., the dosage of urinary sulfa derivatives can be determined and the presence of benzene in the exhaled air can be investigated.

We applied the Folin gravimetric method to determine the urinary sulfa derivatives. We took urine specimens before and two hours after terminating the experiment when—according to various authors—the elimination of sulfa derivatives, caused by the absorption of benzene, is maximal.

For benzene verification in exhaled air we used the following procedure: the air exhaled by the test subject during the final minutes of the experiment is collected in a hog bladder, it is subjected to effervescence (bubbling) with the use of a suitable pump (Orsat apparatus) in a solution constituted by 10 cc of H_2SO_4 and 1 cc of 40% formaldehyde. The presence of benzene in the bubbling air causes brownish-red discoloration of the solution, which is colorimetrically compared with a solution sample containing 1% nitroprussiate of sodium. With the aid of a suitable scale, benzene concentration in the exhaled air is determined from the number of pumping strokes (pompate) needed to obtain a coloration similar to the color of the control sample.

The obtained results are shown in the Table, see next page.

On the basis of these results we exclude the possible percutaneous penetration of benzene under the testing conditions adopted by us, i.e., with intact cutis, by means of contact between liquid benzene and a limb surface including the hand and two thirds of the forearm, during 25 to 35 minutes.

The above statement is confirmed by the collected data, primarily by the constant absence of benzene, even in minimal traces, from the air exhaled [7] by the subject at the termination of the experiment; secondly, the above is confirmed by variations of urinary sulfa derivative excretion which do not exceed physiologic fluctuations con-

[Table I omitted in printing]

sidered normal (Vigliani and Gemelli: maximal daily variation = ± 7; hour by hour variations = ± 2).

Moreover, we found that none of the tested subjects complained during or after the experiments about disorders of a general or local type which could be interpreted as benzene intoxication symptoms; nor were alterations or lesions of any kind found on cutis surfaces exposed to contact with the toxin.

We therefore share the opinion of researchers who contend that the penetration of benzene into the organism through the skin is impossible and [8] that the problem is not significant for practice. The penetration did in fact prove to be non-existent, even when testing methods were applied which involved direct contact maintained to the limit of the test subject's sensitivity, according to systems which do not only reproduce, but even emphasize systems used in industrial practice.

SUMMARY

An experiment was carried out to study the possibility of benzene being absorbed through the skin. Three sound men were subjected to the immersion of their hands and forearms in commercial benzene for 25-35 minutes. Urine sulfates were then determinated and researches made for benzene in the expired air. No benzene was found in the air expired by the subjects at the end of the experiment; no modification was noted in the inorganic-total urine sulfates ratio. The possibility of a percutaneous passage of benzene in the experimental conditions adopted is therefore rejected.

[Exhibit 2-47 (listing references omitted in printing)]

OSHA TRANSLATION

OSHA-76-60

Med Lavoro
37:151-56, 1946

IS PERCUTANEOUS BENZENE ABSORPTION POSSIBLE?

By

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(Director: Prof. Enrico C. Vigliani)

Percutaneous penetration is mentioned among the penetration modes of benzene into the human organism. We refer to Santesson (1897) (Ref. 1), who was one of the first researchers to state that such a possibility definitely exists. His experimental research was carried out in rabbits to the cutis of which pure benzene packs were applied after removal of the fur; the packs were kept in place with bandages. Subsequently (1925) Mauro (Ref. 2), obtained a similar result when testing chemically depilated guinea pigs: packs of pure benzene were applied for 2 hours each for two days. Said author, while never able to verify death among these animals, observed modifications of the morphologic-hematic aspect, a definite indication of starting intoxication.

Lazarew, Brussilowskaja, Lawrow and Lifschitz (Ref. 3) kept the paw of a rabbit immersed in a benzene bath, while preventing the animal from inhaling vapors originating from the bath; they likewise determined the presence of benzene in the exhaled air and therefore reached the conclusion that percutaneous absorption of the solvent is possible.

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At variance from the above, K. B. Lehmann and F. Flury (Ref. 4), in [2] their monograph on solvent pathology, state that the penetration of benzene through the cutis should be considered from a theoretical standpoint only, since they were never able to determine the percutaneous absorption of the toxin chemically.

Recently, the problem was re-examined by Petrilli (Ref. 5). This author experimented with five groups of guinea pigs. Each group included three guinea pigs weighing 450 to 600 g each. The five groups differed as follows: No. 1 guinea pigs with intact fur; No. 2 fur sheared off with scissors; No. 3 depilated with a razor; No. 4 depilated with chemical agents; No. 5 control animals. Benzene was applied to them by means of vaporization while the animals were sealed in appropriate devices; their heads were kept outside of the environment containing the vaporized solvent. The overall result of the investigation revealed that the animals of Groups No. 1—of primary interest here because they were intact—showed slight intoxication symptoms on the 4th day; but only two of the three animals were affected. The author states that the animals showed cutaneous changes on the 6th day, evident to the unaided eye, such as hyperemia, edema, scaly skin lesions; he believes that benzene is able to break through the cutaneous barrier, even in some cases when said barrier is intact.

A critical evaluation of the research work carried out by the cited authors prompts us to divide their work into two groups; the first includes Santesson and Mauro's studies and the second those of Lazarew, Brussilowskaja, Lawrow and Lifschitz and Petrilli.

The investigations of Santesson and Mauro are of considerable interest insofar as these authors were among the first to provide some data on slow benzene intoxication. But the possibility cannot be entirely excluded that [3] the animals on whom the benzene packs were applied might have inhaled the toxin. Therefore the work of these authors cannot be taken into consideration for the purposes of present study. On the other hand, said authors mainly intended to investigate the first symptoms of slow benzene intoxication.

The research work of Lazarew, Brussilowskaja, Lawrow and Lifschitz and of Petrilli are subject to criticism insofar as it cannot be ascertained whether the cutis of the animals treated by them were entirely intact. In fact, Petrilli found macroscopic cutaneous lesions already on the 6th day of treatment, while the first slight intoxication symptoms appeared only two days earlier. The possibility can therefore not be entirely excluded that cutaneous lesions caused by fur shaving or by the prolonged effect of benzene on the cutis—while roughly determinable only—could already have been active during the days preceding the appearance of the initial symptoms.

* * * *

Since the actual status of the problem had reached this point, we believed that a study of the question would by useful, also in view of the authoritative statements made by Lehmann and Flury.

We used men free from skin lesions as test subjects. A few days before the experiment, we prescribed a diet rich in carbohydrates (bread, potatoes, etc.) and green vegetables. The diet contained very little protein, so as to reduce matter causing intestinal putrefaction to a minimum.

Each test subject was placed nude into a metal tank for 20′ to 30′. The tank had a capacity of 8,317 mc and was perfectly airtight. The head of the subject remained outside, for which purpose the tank lid had an aperture; rubber sleeves prevented the escape of air from the inside of the tank to its exterior, and sealed the aperture through which the subject's neck was [4] passed. Moreover, after closing the subject's nostrils with a clasp, a mask was applied. The subject breathed through the mouth, using the 5 meter-long rubber tube fitted to the mask, and inhaled air originating from a courtyard beyond the chamber where the tank was located; the tube passed through a window. A benzene-saturated atmosphere was obtained in the tank by introducing several cotton wool pads soaked with the solvent. Furthermore, the subject applied liquid benzene to his skin within the tank, using cotton wood pads, also saturated with the solvent (see Fig. 1).

[Figure 1 omitted in printing]

Urine eliminated before the subject was placed into the tank, eliminated immediately after placement in the tank, one hour and two hours later was used for the determination of total inorganic sulfates with the aid of the Folin gravimetric method.

[5] We wish to premise, so as to justify the research work and sulfate dosage as well as the ratio between inorganic sulfates: total sulfates, that the research work of Yant, Schrenk, Sayers, Horwarth and Renharth (Ref. 6), Yant, Schrenk and Patty (Ref. 7), Gueffroy and Luce (Ref. 8), Vigliani and Giannini (Ref. 9), Girino (Ref. 10), Vigliani and Gemelli (Ref. 11) showed a rapid and significant decrease in the ratio between inorganic sulfates and total sulfates. As a consequence of benzene absorption, the first diminish while the second increase. The modifications reach their maximum two hours after the termination of the test subject's exposure to benzene vapors.

Urine sulfate dosage determination is carried out with the Folin method, which we will briefly describe here.

INORGANIC SULFATES.—25 cc urine is filled into an Erlenmeyer of 200 to 250 cc; then 100 cc H_2O and 10 cc HCl, diluted in H_2O with a volumetric ratio of 1:4 is added. 10 cc of an aqueous 5% $BaCl_2$ solution is added drop by drop during continuous agitation with a glass rod. The mixture is left standing for one hour; filtration of the same follows through a Schleicher-Schull filter (blue band); the filtration is carefully accelerated, using a vacuum bottle connected with a water pump. The filter is burned in a porcelain crucible which had been accurately weighed; the crucible is kept at a temperature of 700 to 800° for a couple of hours. Cooling follows in the desiccator and a final exact weighing is performed.

The weight difference in mg is the (weight of) inorganic sulfates contained in 25 cc of urine.

TOTAL SULFATES.—25 cc urine and 20 cc HCl, diluted as specified above, are filled into an Erlenmeyer of 200 cc capacity. Boiling for at least 20′ follows, while the Erlenmeyer's outlet is covered with a crucible slide [6] (vetrino da crogiolo) which has the overall function

of cooling, heating and regulating the boiling process, moderating the same to prevent the desiccation of the container.

The container is then cooled under running water for 2′-3′; 50 cc of H_2O is added; then 60 cc of 5% $BaCl_2$ is added drop by drop during continuous agitation with a glass rod. The next steps are similar to the procedure followed in case of inorganic sulfates.

[Table omitted in printing]

[7] Our investigations show that the ratio inorganic sulfates, total sulfates was not significantly modified as a consequence of cutis exposure to benzene vapors and simultaneous cutaneous application of the liquid solvent. The observed slight variations are within the limits of fluctuations found in normal subjects, since the S.I. : S.T. ratio is near-constant at various hours of the day; fluctuations generally do not exceed ± 2%. (Vigliani and Gemelli). (l.c.).

In addition to the examination of urine sulfates, we also investigated the benzene content of air exhaled by the same test subjects. For this purpose, the apparatus suggested by the British Home Office was used, previously tested in this Clinic by Vigliani and Reina (Ref. 12). The apparatus proved to be suitable for the determination of minor solvent volumes in the exhaled air as well, and it is suitable for the qualitative verification of traces.

The apparatus consists of a mechanism to activate bubbling of the exhaled air through a solution of formalin in concentrated sulfuric acid. The presence of benzene causes brownish discoloration of the solution, which is more or less accentuated. The color is comparable to a test tube containing a 1% solution of sodium nitroprussiate. Starting from the air volume needed for bubbling, so as to obtain a color equal to the sample color, the benzene concentration in the air is determinable with the aid of a suitable calibration table.

The examination of benzene in air exhaled while the test subjects remained in the tank and while their cutis was exposed to benzene vapors and kept in contact with liquid benzene, always resulted negative.

Another investigation involved the application of ample cotton wool [8] layers soaked in pure benzene on the

[Figure 2 omitted in printing]

cutis of an upper limb of all test subjects. These remained on the limb which was kept in a cardboard tube, sealed at its end and perfectly airtight, fitted with rubber sleeves (see Fig. 2). During the final minutes of the test, for approximately 20′ to 30′, the possible presence of benzene was examined in the air, with the aid of the above-mentioned method. Not even traces of the solvent could ever be determined nor recovered in any of the performed experiments.

In view of our experiments, we can therefore exclude a percutaneous absorption of benzene, at least to any appreciable extent, through intact cutis.

SUMMARY

An investigation was performed to determine whether benzene absorption through the intact cutis of man is possible. The cutis of the trunk and the limbs of 8 sound subjects were exposed for 20′ to 30′ to contact with [9] benzene vapors and liquid benzene, with the aid of instrumentation which excluded any eventual solvent inhalation. The absence of significant inorganic sulfates/total sulfates ratio modifications and the absence of benzene vapors in the exhaled air led us to conclude that no benzene is absorbed, (at least not to any appreciable extent) percutaneously by man, provided that the cutis is intact.

We reached the same conclusion from negative results obtained during benzene verification in the air exhaled by the men, following application of cotton wool layers saturated with the solvent in the cutis of an upper limb which was kept airtight in a perfectly sealed cardboard tube with rubber sleeves.

[Exhibit 2-69 (list of references omitted in printing)]

OSHA TRANSLATION

OSHA-76-56

Med. Pracy
12:413-26, 1961

ABSORPTION OF BENZENE THROUGH THE SKIN IN MAN

By

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It is generally understood that many organic substances have the ability to be absorbed through the undamaged skin. The function of the skin as a path of absorption is strongly emphasized—or on the contrary, omitted—mainly according to the extent of accumulation of clinical data on intoxication which were caused by the absorption of the given toxic substance through the skin. In regard to benzene, the view is generally accepted that it has the ability to be absorbed through the skin, but to an extent which does not induce intoxication. It is also accepted in practice that the sole essential path of benzene absorption under industrial conditions is the lungs.

Due to the expanded use of benzene as a solvent in some sectors of production and the appearance of cases of chronic intoxication, the question of the function of the skin as a path of absorption has once again become urgent, both from the standpoint of prophylactic activity and in consideration of the need for elucidating the clinical symptoms of absorption which have been observed (R. Vlasak, 1959).

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Current information on the absorption of benzene through the skin is primarily based on two research studies whose results were contradictory.

Lazarev, Drussilovskaya and Lavrov (1931) conducted tests on rabbits and [2] mice. Contact of the skin with liquid benzene was accomplished by immersion for several hours of the animal's ear or paw in liquid benzene. The amount of benzene absorbed they considered the quantity of benzene in expired air, as determined by burning to CO_2 and subsequent conductometric measurement of the absorbing solution. The rate of absorption of liquid benzene was determined at 0.05 mg/cm²/min (i.e., 3 mg/cm²/hr). With this rate of absorption it had to be taken into account that the authors, in not analyzing the excretion of benzene from the body through other paths, considered the absorption rates obtained as underestimated values.

The authors themselves also studied the absorption through the skin of animals of benzene vapors, protecting against their absorption through the respiratory tract. As an indication of absorption, the reference concentration of phenol in the urine was adopted: it increased in animals under examination. The results of the test were interpreted by positive quantitative methods.

Two arguments militate against the mechanical transposition of the results of this study to humans working in contact with benzene: a) the method of administering benzene to the animals induced profound changes in the physiological stage of the skin, leading to total mummification of the exposed portion of the body. The results of absorption obtained under such conditions may not be interpreted as absorption through undamaged skin; and b) it must be assumed that there may exist certain differences between the permeability of the skin of animals and men, linked to the differences in anatomic structure and skin function.

For the above reasons, the question was raised again by N. Caesaro (1946) who ran tests on humans involved with both the absorption of liquid benzene and its vapors. In the case of liquid benzene, he wrapped the arm in a cotton compress saturated with benzene. Adopted as the

measure of benzene absorbed: [3] a) the amount of benzene vapor in expired air; b) analysis of a drop in so-called sulfur ratio* in the urine. Both factors produced negative results, from which the author concluded that benzene absorption through the skin did not play a role in industrial exposure.

In that study, a limitation was indicated by the benzene absorption factor, since it is understood that it is analyzed with low sensitivity. A definitive drop in the sulfur ratio occurs primarily during absorption through the lung of benzene vapor in concentrations close to the industrial norm, i.e., about 0.1 mg/liter**. The negative result of sulfate tests can not be considered as sufficient negative proof in a discussion on benzene absorption.

Teisinger and Fiserova-Bergerova (1955) developed an interpretation to evaluate benzene absorption based on the analysis of phenol in the urine in man. This factor is very sensitive and permitted perception of changes in phenol excretion in the urine owing to the absorption of trace quantities of benzene.

The goal of this study was a quantitative analysis of the rate of absorption of benzene through the skin in man, wherein it was attempted to evaluate the role of the skin as a path of absorption of benzene under industrial conditions.

The following criteria of absorption were used in this study:

1. Determination of excretion of phenol in individual urine fractions at least one day long; interpretation of results obtained according to data of Teisinger and Fiserova-Bergerova.
2. Chemical analysis of the amount of absorbed liquid benzene by the method described below, developed specially for that purpose.

[3a] Tests conducted included:

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* As a result of binding of phenol into sulfuric acid esters, the amount of ester sulfate in the urine is increased at the expense of inorganic sulfates, causing a drop in the total sulfur ratio, which under physiological conditions, constitutes from 75-95%.

** This normal is now usually considered high; GOST allows a concentration of 0.02 mg/liter ever since 1959.

a) absorption of liquid benzene administered either with aid of insulated plate or using a slide (according to method of evaluation employed);

b) absorption of benzene vapors through the skin, where excretion of phenol in the urine is used as an indicator.

RESEARCH METHODS

1. DIRECT ANALYSIS OF BENZENE ABSORPTION THROUGH THE SKIN

[4] A method was developed which may be used in testing the rate of absorption not only of benzene, but also of other volatile solvents. The principle of the method does not deviate from that previously used in our institute for studies on less volatile compounds such as aniline (J. Piotrowski, 1957) and nitrobenzene (J. Salmowa and J. Piotrowski, 1960). An accurately measured amount of the substance is applied to the skin, making contact there for a specific period of time. By analyzing the excess of the substance in terms of a final test the amount of absorbed substance may be determined from the difference and thereby the rate of absorption. So far, a condition for the use of this method was the careful protection against losses occurring from the evaporation of liquid during the test.

In the case of benzene, protection against evaporation by means of insulation has been inadequate in view of its high volatility. An innovation of the new method is the use of the volatility of the compound being studied as a basis in analyzing absorption.

This method is carried out as follows: a small amount of benzene (0.02 ml) is applied by microsyringe to a watch crystal which is then pressed to the skin of the forearm with an elastic. The glass is placed under a funnel having a slightly larger diameter which, with the aid of short elastic connection pieces is connected to a water suction pump through a rinsing machine with a porous glass containing 20 ml of nitrating mixture (10% ammonium nitrate in concentrated sulfuric acid) as an

absorbing solution. This system is under a stream of cleansing air which washes the glass at a rate of 0.5-1 1/min (Fig. 1).

When the test is over the rubber connecting the glass and the forearm is cut through, permitting rapid evaporation of benzene; a 15 minute passage of air through the rubber gash is sufficient for total evaporation of excess [5] benzene and flushing the system with air. Individual phases of the procedure are illustrated in Fig. 2.

[Figures 1 & 2 omitted in printing]

Similar tests have been conducted on the same glass unit (without use of an exposed person) to establish a reading which corresponds to the amount of benzene applied. Benzene absorbed in the rinser in the form of m-dinitro-benzene is analyzed absorptiometrically with acetone and lye. For this purpose, the contents of the rinser are put aside until the following day to permit complete nitration, after which it is diluted to 1 liter with distilled water. Twenty milliliters of an aqueous solution are taken from the flask after thorough mixing. [6] The results of analysis with the same glass unit corresponds directly to the amount applied. Quantity of benzene remaining on the glass and skin after absorption test is calculated from the model:

$$m = \frac{A \cdot m_o}{A_o}$$

where m_o is the amount of benzene applied to skin, mg;

A_o is the sample absorption in test made on glass unit;

A absorption of sample in test on skin.

The amount of benzene absorbed ($m_o - m$) we divided by the glass surface (cm^2) and the skin contact time (hours). The result obtained is expressed as a rate of absorption ($mg/cm^2/hr$). The appropriateness of the procedure was verified in a way that the measured quantity of benzene was applied to the glass and brought in contact with the skin, after which contact was complete and it evaporated. In this way, we obtain an approximate exposure time $t = 0$. The results of this procedure did not show any difference versus analysis with

the same glass unit, due to which it was included in method calibration.

The precision of the quantitative analysis of benzene is ± 5%. The error is mainly the result of the final absorptiometric method of analysis, with whose aid no better results could be obtained. In view of the insufficient accuracy obtained here for a single measurement, the following conditions were stipulated to attain unambiguous results;

1. The test is run so that the amount absorbed is about 20% of the amount applied. Under those conditions we obtain a difference in findings (before and after) which is quite great; and the excess amount of substance on the skin does not alter the results of absorption to a significant degree. Consequently, the amount applied on the skin had to be reduced to a minimum, which in turn necessitated us to reject the plates used previously for tightly fitting slides.

[7] 2. Absorption readings for the initial applied amount of benzene were obtained many times to reduce the concomittant error, and as a basis the average was used, its error constituting a mere ± 1.4%.

3. The results obtained in the absorption of benzene through the skin were not interpreted individually, but an average result was adopted whose mean error is sufficiently small (in this test ± 2%).

Due to the conditions observed above, the research findings described hereinafter can be considered to be totally reliable.

2. ANALYSIS OF BENZENE IN THE AIR

In addition to the above methods, and during analysis of the concentration of benzene vapors in the air of the test room, the absorptiometric method with acetone and KOH was used in the Piotrowski modification (1954). Analyses were performed on a Coleman Junior spectrophotometer at a wavelength of 570 millimicrons. As stated, accuracy of analyses with the aid of this method was ± 4%.

3. ANALYSIS OF PHENOL IN URINE AND PHYSIOLOGIC VALUES

To analyze phenol in the urine, the colorimetric method with 2,6-dibromoquinonochloroimide was used in the version described in Teisinger et al. (1956). In this method, the phenol is analyzed after distillation from the urine from an acid medium as total phenol (free or esters).

In the initial tests it was found that the amount of reagent in the formula is insufficient to achieve conformity with Beer's law over a sufficiently large range of phenol concentrations. For 50 micrograms of phenol, this relationship is illustrated in Fig. 3. On the basis of the chart in Fig. 3, the amount of reagent was fixed at 0.25 ml and the entire analysis had the following procedure:

[8] 5 ml of urine to be studied with addition of 0.5 ml concentrated sulfuric acid is distilled in a glass apparatus (slides) with water vapor at a rate of up to 10 ml/min to obtain 50 ml of distillate. An optimal quantity is taken from the distillate (2.5 - 10 ml) and placed in a 25 ml flask; 2.5 ml of buffer (pH 10.15) is added (10.5 g $Na_2CO_3 \cdot 10\ H_2O$, 2.8 g anhydrous borax dissolved in 0.5 liters water) and 0.25 ml of alcohol solution of 2,6-dibromoquinonochloroimide (15 mg/10 ml), filling with water to make 25 ml; after 1 hour, readings are made on the Coleman Junior device (cell 25 x 105 mm; wavelength 610 millimicrons).

Calibration of the method * was done in the range up to 30 gamma of phenol in the sample; accuracy of analysis ± 6%.

[Figure 3 and Table I omitted in printing]

[9] The results of phenol in the urine analyzed by this method in different persons are illustrated in Table I.

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* In this example in the cited study of Teisinger et al., to make up specimen solutions of phenol (page 74, paragraph 1), theoretical error crept in; the solution made according to this formula would have a concentration not 10, but 25 gamma/ml.

COURSE AND RESULTS OF TESTS

1. ABSORPTION OF LIQUID BENZENE

A. STUDY OF THE RATE OF ABSORPTION BASED ON EXCRETION OF PHENOL IN URINE.

Five tests were carried out as follows: persons were exposed on the bare forearm* and a plate with benzene-saturated cotton was placed on the forearm (about 0.06 g/cm²). This plate was insulated with the aid of cellophane affixed to the forearm with adhesive tape. The contact area was 35-45 cm², contact time 1.25-2 hours. To eliminate absorption of trace quantities of benzene vapors (from the plate) through the lungs, the forearm was placed under a hood with an intense crossflow of air. In addition to a digestorium, the air was analyzed for its benzene content for purposes of control; the results were negative.

The urine samples were taken for an entire day, every 1-3 hours, and less often at night.

Excretion of phenol in the urine. In these tests, phenol excretion in the urine was low; daily amounts of excreted phenol ranged from 8.0 to 14.7 mg, which only slightly exceeds average values, and is completely within the boundary values of physiologic excretion given by Teisinger et al., (average 8, maximum 20 mg/day).

The physiologic values obtained by us were expressed either as concentrations (mg/liter) or as rates of excretion (mg/hour). The extreme values ob- [10] tained in tests on absorption are presented below, in comparison with the extreme physiologic values obtained by us (Table II).

[Table II omitted in printing]

As can be seen from Table II, the maximum rates of phenol excretion in persons exposed to benzene were much higher than the corresponding values confirmed by us. An increase in phenol excretion in the urine after

* Data are from self-experiments and from research on volunteers at the Institute of Labor Medicine.

exposure showed up most clearly in a comparison of the excretion curves (example given in Fig. 4). In this figure three curves of changes in phenol concentrations in the urine and the rate of excretion of the urine itself (A) are plotted, and their product being changes in the rate of phenol excretion (B); the latter curve appears to be most typical.

Although the very fact of increased phenol excretion in the urine after exposure to liquid benzene through the skin seems to be indisputable, a proper calculation of phenol surpluses caused by absorption of benzene runs into many problems. It is associated with the very great variability of physiologic values (example in Fig. 5). Taking the rate of excretion before exposure individually in each person as the standard, is quite impossible to the small number of such measurements; the average value before and after the test is slightly exaggerated, since we only have data obtained after the passage of [11] one day, when excretion is likely to not have reached physiologic values; adoption of the mean value established in most data from different individuals is impossible since the average (0.24 mg/hour) is much higher than the average from data obtained in persons exposed before the test (0.16 mg/hour). Certain arguments can be given in favor of using each of these methods.

[Figures 4 and 5 omitted in printing]

[12] It was found that the results would have less error if physiologic excretion was calculated as the average of all four methods of calculation. The results obtained thus are presented in Table III.

[Table III omitted in printing]

For a basis of evaluation of the amount of absorbed benzene, Teisinger et al. (1956) were followed in that the average of about 30% of absorbed benzene is excreted in the urine in the form of phenol. On that basis the rate of absorption of liquid benzene through the skin was calculated in individual cases (Table IV).

The average rate of absorption of liquid benzene through the skin, calculated in this way, constitutes about

0.24 mg/cm²/hour. In view of the number of assumptions made in the course of calculation, this value should be taken only as a reference value.

On the periphery of tests on phenol excretion, primary data was gathered on the characteristics of excretion of this metabolite. We were interested in the rate of excretion which was characterized by a constant K equation of the first order. The calculation was done on the basis of statistically calculated equation of regression (Fig. 6). Excretion constant is approximately 0.12/hour, on the average; and this is on the same order as the constants of excretion of metabolites of other aromatic compounds studied (p-aminophenol in application [13] of aniline or nitrobenzene; p-nitrophenol in the application of nitrobenzene to test animals). This value should be interpreted as referential, since it was calculated on the basis of too meager data and for very small doses of benzene. It is not precluded that phenol excretion is dual-phased, wherein the drop in the rate of excretion would be faster in the first stage: but the data we have is too meager and too one-sided to document this hypothesis in a manner which would not be suspect.

[Table IV omitted in printing]

B. ANALYSIS OF THE RATE OF ABSORPTION OF LIQUID BENZENE THROUGH THE SKIN BASED ON DIRECT CHEMICAL ANALYSIS

The method of test performance was done as described. Watch crystal used had an area of 8 square cm; contact of benzene applied to the glass (0.02 ml = 17.6 mg) with the skin lasted 1.25 hours. A total of 15 calibration measurements and 7 absorption measurements on the forearm skin were made in different persons. Calculation based on the data illustrated in Table V.

The average surplus of benzene from the watch crystal, caused by absorption of benzene through the skin, was:

$$x = \frac{0.110}{0.490} \cdot 17.6 \text{ mg} = 4.0 \text{ mg}$$

The average rate of absorption, with respect to area and time of contact, was:

[Figure 6 & Table V omitted in printing]

[14]
$$v = \frac{4}{8 \times 1.25} = 0.4 \text{ mg/cm}^2\text{/hr}$$

The results obtained by the direct chemical method (0.4 mg/cm²/hour) and the indirect method based on phenol excretion in urine of persons exposed (0.24 mg/cm²/hr) are quite comparable. From the standpoint of methods, however, we feel that the first of them (0.4), using the direct method, is quantitatively more sure. It should be noted that the results pertaining to the rate of absorption of liquid benzene through the skin refer to the extreme case, where the skin of the exposed individual is completely dampened by benzene at the point of contact; these are thus maximum values.

[15] 2. ABSORPTION OF BENZENE VAPORS THROUGH THE SKIN

Tests on the absorption of benzene vapors through the skin were done in a special toxicology chamber designed for this type of experiment (Dutkiewicz, 1960).

A total of three tests were run. The concentration of benzene vapors was 1.0 mg/liter; control analyses were made every hour and they showed that concentrations did not vary by more than ± 5%. The air temperature in the chamber was 25°C, and humidity was about 35%. The test subject was placed in the chamber without clothes. Before and after exit from the chamber, the test subject took a bath. To prevent contemporaneous absorption of benzene vapors in the respiratory tract while spending time in the test chamber, the person breathed pure air through a mask attached inside the chamber.

Evaluation of absorption of benzene vapors through the skin was based on analysis of phenol excretion in the urine. Urine samples were taken for one day before the test to establish physiologic levels of phenol in the urine. Then urine was taken during and after completion of exposure, also for the period of one day.

The results were evaluated on the basis of the amount of phenol excreted in the daily quantity of urine, considering the physiologic excretion established before the experiment in the given individual.

In the first test, exposure lasted 1.5 hours; no increase in phenol excretion was detected in the exposed individual's urine.

In two subsequent tests, exposure was extended to 7 hours. The increase in phenol excretion over the course of a day constituted 2.7 and 4.2 mg, respectively. For an average quantity, about 3 mg phenol per day, the likely amount of absorbed benzene is about 10 mg. This quantity is quite negligible, [16] if we consider that at the same concentration of benzene in the air (1 mg/liter) and pulmonary ventilation of about 3 m^3/7 hours*, the amount of absorption through the lungs would be about 1500

* In sitting position, without additional exertion.

mg**. Thus absorption of benzene vapors through the skin is less than 1% of the amount absorbed under the given conditions through the lungs. This quantity is small enough to warrant the conclusion that benzene vapors do not tend to be absorbed through the skin.

DISCUSSION OF RESULTS AND CONCLUSION

The rate of absorption of liquid benzene through the skin in the case of total moistening of the skin of the forearm with benzene in men is about 0.4 mg/cm^2/hr. This rate is of the same order as was found in previous studies for aniline and nitrobenzene. But, considering the relatively lower toxic effect of benzene as compared to those compounds, the rate of absorption of liquid benzene should be considered low. It is also essential that single moistening of the skin or clothes with benzene does not cause, in view of its great volatility, prolonged danger to the skin, as occurs in the case of aniline or nitrobenzene. Furthermore, protection of the skin against absorption of benzene should not offer any problem, with the exception of some jobs.

We should note that on jobs where moistening of the skin is continually renewed, e.g., in manual painting with paints containing benzene as a solvent, and in work of similar type where contamination of the skin with paints might furthermore be a comparatively persistent container of benzene, the absorption of benzene through the skin might play a more substantial role. Assuming that the area of both palms is 600 cm^2, the maximum amount of absorption in the course of 8 hours of work might be about 2,000 mg. This quantity would still [17] not cause acute intoxication, hence the lack of data on acute benzene intoxication through skin absorption. At the same time, it is very serious from the viewpoint of chronic intoxications. We feel that current increased tolerable concentration of benzene vapors in the air of 0.1 mg/liter effective in Poland is related to absorption of just about the order of 300 mg per day*, and the concentration per-

** Considering retention in the lungs about 50%.

mitted by GOST (0.02 mg/liter) is about 60 mg. Thus absorption of liquid benzene through the skin in manual work can not be neglected, as least as an additional path of absorption.

Absorption through the skin of benzene vapors is not, it would seem, any toxicologic problem.

(Authors thank U. Neuhorn for technical aid in carrying out research).

SUMMARY

The absorption of benzene throughout the skin in men in experimental conditions was examined. The liquid benzene was absorbed with the velocity about 0.4 mg/cm²/hr; the absorption of the benzene vapors was insignificant and it did not exceed 1% of this absorbed throughout the respiratory ways in the same conditions. The study was based on the determination of phenol contents in urine and on the new direct chemical method for the designation of skin absorption of benzene, the method described in the paper.

The authors concluded that the absorption of benzene throughout the skin must not be neglected.

[Exhibit 41-28]

Executive Office of the President

COUNCIL ON WAGE AND PRICE STABILITY
726 Jackson Place, N.W.
Washington, D.C. 20506

Dr. Eula Bingham
Assistant Secretary for
Occupational Safety and Health
Administration
Department of Labor
Room S-2315
Washington, D.C. 20210

Dear Dr. Bingham:

I am writing to offer comments for the public record on the proposed benzene exposure standard. The Council's basic concern with inflation, of course, motivated these comments which are detailed in the attached appendix and briefly summarized below.

At the outset, I am pleased to note one significant improvement which distinguishes this proposal from other recent OSHA health regulations. Less emphasis than usual is placed on engineering controls as the required means of compliance. The proposal allows firms to select any mix of work practice controls and engineering controls which will keep benzene exposure levels below those specified in the standard. By proposing some flexibility in approaches to compliance, OSHA is creating desirable incentives for firms to find the least costly means of protecting worker health. As explained in our attached comments, we think OSHA should move even further in this direction.

We are troubled, however, by certain other aspects of this proposal. We think the proposal does not reflect sufficient consideration of the costs and attendant health benefits of the standard. Given the inadequacies of

OSHA's Economic Impact Analysis (which we discuss in the appendix), we think the economic feasibility of this proposal has not yet been demonstrated. For example:

1) Compliance costs for a major sector of an industry (facilities for bulk and terminal storage of gasoline operated by independent wholesalers) have been excluded from the total compliance cost estimate. The EIA separately puts this sector's compliance cost at $4 billion but then disregards that cost on the grounds such facilities would be phased out of service in the face of this prohibitive cost. It seems unreasonable to imply that forcing wholesalers out of business or dispensing with the service they provide is without cost to society.

2) Costs to tire manufacturing and related industries are understated. The EIA assumes substitutes will be found for benzene which will make unnecessary any capital outlays for engineering controls. Yet there is no discussion of the cost or availability of suitable substitutes.

We also think the proposal and its EIA lack adequate analysis of alternative exposure levels and implementation plans, as more fully explained in the appendix. For example:

1) There is no discussion of using the "action level" approach employed in other health regulations. Such an approach could (a) provide an extra margin of safety, (b) make unnecessary the present proposal's exemptions (such as gasoline distributors and industries using liquids containing very little benzene, where workers could conceivably be exposed to hazard), and (c) lessen certain recordkeeping and measurement costs.

2) In work places where the per person cost of exposure reduction is particularly high *and* where exposure is of a sporadic nature, some consideration should be given to alternative, less costly methods of assuring protection. Yet the feasibility of such alternatives, such as the use of respirators, is not carefully addressed in the proposal or the EIA.

3) We also wonder if OSHA has estimates of the incremental reduction in health risks which are associated with the reduction in exposure levels from 10 to 1 ppm.

On balance we think the proposal is not yet ready for adoption. We urge OSHA to improve its economic analysis of the proposed standard and to revise the proposal so it will assure worker health protection at the least possible cost to society. We think this can be accomplished without excessive delay, and in the interim vigorous enforcement of the existing emergency temporary standard can serve to protect worker health from the dangers of benzene exposure.

If you or your staff would like to discuss this further, please contact me (456-6466) or Ms. Dianne Levine (456-6429) who has been monitoring the benzene standard here.

Sincerely yours,

Barry P. Bosworth
Director

APPENDIX: ANALYSIS OF PROPOSED BENZENE STANDARD

Synopsis

The Council on Wage and Price Stability is concerned that the proposed standard does not reflect sufficient study of the costs and attendant health benefits of some very costly parts of the standard.[1] OSHA has not fully documented its case for adopting the proposed benzene exposure limit rather than a more *or* less stringent one. In addition, having decided upon the 1 ppm standard OSHA has not adequately considered the problem of designing a standard that will foster compliance with minimum cost. A standard that encourages this minimization of cost must be based on detailed estimates of the health risks in all sectors of the affected industries as well as the costs of reducing these risks by varying amounts in each workplace and using different means of controlling exposure. In other words the feasibility, cost and efficacy of alternative modes of achieving compliance with the 1 ppm standard must be analyzed. In so far as is possible the final standard should be flexible enough in the area of permissible means of compliance to enable each industry to adopt those alternatives that present the least cost burden while protecting workers to at least the mandated degree.

[2] Unfortunately the Economic Impact Analysis[2] does not contain the information that would enable OSHA to design such a standard. Cost estimates have not been broken down in sufficient detail to inform OSHA of the per capita cost of reducing exposure to benzene in different workplaces. Moreover the differing costs of this reduction when using varying control methods have not been investigated. It is in the work areas where the per person cost of exposure reduction is unusually high that alternative methods of obtaining the same worker protection should be considered. In particular, the use of respirators for exposures of limited duration (and totalling a minor share of the work week) should be considered.

The Council also strongly urges OSHA to consider the cost-saving advantages of adopting an "action level". The current proposal requires frequent and costly air monitoring and medical surveillance (as well as recordkeeping) in all workplaces where benzene is present. If an action level were adopted as it has been in other OSHA health standards, an initial determination of very low exposure levels (i.e. below the action level) would exempt firms from these requirements. When the work process is changed another measurement would be required to determine whether or not the action level is exceeded. This kind of approach would allow expenses to be cut where dangers are non-existent to workers without increasing the health risks attributable to benzene exposure. Moreover an action level approach would avoid the dangers of exempting entire industries from the regulation. For instance, the [3] proposal does not now cover wholesale bulk gasoline facilities or industries using liquids containing very little benzene yet these could conceivably expose workers to benzene at levels exceeding 1 ppm.

Thus the Council is concerned that a benzene standard be chosen that provides reasonable protection to workers and that once chosen, the standard be sufficiently flexible in terms of compliance so as to impose the least possible cost on society. In both these respects, but particularly the latter, we do not believe that OSHA has presented a proposal that is ready for adoption. We urge OSHA to expand its economic analysis of the benzene standard and to revise the proposal in light of the new information that can and should be developed within a fairly short period of time. In the meantime enforcement of the

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[1] This submission is made on behalf of the Council on Wage and Price Stability, an organization created by the Council on Wage and Price Stability Act (P.L. 93-387), within the Executive Office of the President. The authority of the Council to intervene in governmental rulemaking and ratemaking proceedings, conferred by Section 3(a) of the Act, has been delegated to the Director of the Council (see 40 *FR* 52882). The views expressed in this filing are not necessarily those of the individual members of the Council.

[2] *Economic Impact Statement: Benzene*, Vol. 1 and 2. Arthur D. Little, Inc., (Washington: OSHA May 1, 1977).

emergency temporary standard can serve to protect workers health from the dangers of benzene exposure.

Comments on the Proposal and the Economic Impact Analysis

The Council supports the goal of removing hazards to worker safety and health. Moreover, the Council appreciates the necessity of adopting a conservative or risk averse approach to worker exposure standards involving potential carcinogens and leukemia-causing agents. Yet these efforts to improve the work environment are not without cost, and OSHA is required by Section 6(b)(5) of the Occupational Safety and Health Act to consider the question of "feasibility" in developing its standards. Since OSHA is faced with a finite quantity of society's resources or maximum costs that can be allocated to worker safety and health in any industry, OSHA should pay serious attention to the develop- [4] ment of standards which will deliver the maximum increment of worker safety and/or health from every dollar spent on compliance. In other words, OSHA should search for the least expensive means of reducing the total risk of health impairment attributable to benzene exposure.

The Council notes that OSHA is proposing some flexibility in approaches to compliance with the proposed benzene standard; the proposal allows firms to select a mix, without restrictions, of work practice controls and engineering controls as long as those controls meet the 1 ppm average exposure and the 5 ppm ceiling exposure standard. We believe this is a significant improvement over the approach taken by OSHA in some previous occupational exposure standards.[1] By permitting the use of work practice controls, OSHA has taken a step forward

[1] See Arsenic (40 *FR* 3397), Lead 40 *FR* 45934), Sulfur Dioxide (40 *FR* 54520), Coke Oven (40 *FR* 33268) proposed standards. Under these proposed standards engineering controls must be adopted to reduce exposure levels to the lowest level achievable and then work practic control must be used to further reduce worker exposure. Finally respirators must be used if the above two control methods are not sufficient to reduce exposures to the permissible level.

in the direction of developing a standard that minimizes costs of compliance. However, the ceiling limit of 5 ppm for no more than one 15 minute period per day seriously limits the use of work practices to control worker exposure to benzene and, in effect, requires firms to install engineering controls. A slightly higher ceiling limit would make work practice controls more practicable. Alternatively, the use of personal protective devices in situations of sporadic exposure should be permitted in achieving compliance with the 1 ppm standard. In making these changes in the proposal OSHA would be allowing firms to choose the least cost means of complying with the standard.

[5] Additionally, there are certain inadequancies of the Economic Impact Analysis (EIA) which we would like to identify. Our comments note these inadequacies, first discussing the EIA of costs and then benefits. Finally we offer a few observations concerning regulatory alternatives.

Analysis of Costs

The Economic Impact Statement for the proposed benzene standard estimates that the total cost of compliance is about $267 million in initial capital costs, $124 million in additional first year operating costs, and $74 million in additional recurring operating costs in subsequent years.

Two significant problems exist with the cost estimates —both of which may lead to underestimates of the costs. First, a major sector of an industry and its costs of compliance have been excluded from the total compliance cost estimate. The language of the May 27, 1977 proposal, while clearly excluding "retail automotive service stations", does not exempt bulk storage facilities. A recent addendum to the proposed standard published in the *Federal Register* of June 24, 1977 (42 *FR* 32263), specifies that "the storage, transportation, distribution, dispensing or sale of gasoline as a fuel subsequent to the discharge from bulk terminals" will not be covered by the final permanent benzene standard. However the bulk plants or terminals themselves and the wholesale petro-

leum facilities are still included under the proposed standard. Arthur D. Little, Inc., notes that its estimates of the costs of compliance for bulk storage of gasoline and terminal storage of gasoline exclude facilities operated by independent wholesalers even though these facilities are covered by [6] the proposed standard.[1] As a result, the total costs of compliance have been severely underestimated. A separate section of the economic analysis estimates that the cost of bringing these facilities into compliance would be almost $4 billion or about $200,000 each. These costs are excluded from the total compliance cost estimates, presumably because "it is expected that secondary bulk plants would be phased out of gasoline service before incurring an investment of almost $200,000 each."[2] Even if these wholesalers are forced out of business or are merged into a major oil company, these functions will need to be performed. Thus, like facilities would still have to be brought into compliance at an estimated cost of $4 billion. The probability that secondary bulk plants would be forced out of business suggests that the regulation is *prima facie* infeasible at least as to that part of the industry and may well be infeasible as a whole.[3]

The second source of compliance costs that has not been considered in the analysis involves possible higher costs of substitute solvents and the costs of finding and introducing these solvents in tire manufacturing and in miscellaneous rubber products industries. The only costs of compliance considered in these industries are those of monitoring, medical surveillance, respirators, personal protective equipment, [7] training, recordkeeping, and

[1] *Economic Impact Statement, ibid.*, p. 1-8.

[2] *Economic Impact Statement, ibid.*, p. D-37.

[3] It is clearly a legal judgment as to whether a standard is "feasible" within the meaning of the OSH Act in specific factual circumstances. However, it is generally acknowledged that bankruptcy is a *prima facie* indication of economic infeasibility. Our position is that infeasibility as that term is normally used with regard to economic matters occurs at a point well prior to bankruptcy; a substantial number of authorities support that position.

signs. No capital costs are listed because of the presumption that substitutes will be found for benzene. A correct approach to costs of compliance necessitates inclusion of capital costs of engineering controls if feasible or a discussion of the cost, suitability and availability of substitutes for benzene in these production processes.

Analysis of Benefits

The Council is well aware that benzene has been shown to be a cause of leukemia. However the studies that have demonstrated this cause and effect relationship involved exposure levels that were many times higher than the 10 ppm of the currently existing standard. Over time there has been a substantial decrease in worker exposure levels so that now few if any workers are actually exposed above 10 ppm. American consumers as well as American workers are entitled to know what the benefits are of reducing the occupational exposure level for benzene from 10 ppm to 1 ppm.

While the Council in no way wishes to question the expert opinions of those scientists who have examined the data and concluded that benzene is a serious hazard to worker health,[1] we would expect [8] a more detailed analysis of the magnitude of the health risk in each industry and plant affected. The number of cases of leukemia that can be expected to occur in each plant as a result of current exposures to benzene can be calculated using data that are currently available. The Economic Impact Statement estimates that 191,000 workers are

[1] *NIOSH Criteria Documents for Benzene* revised August 1976. Andjelkovic, D., Taulber, J. and Symons, M., "Mortality Experience of a Cohort of Rubber Workers, 1964-1973," *Journal of Occupational Medicine;* 18, 6; p. 387-394 (1976); Infante, P. F., Rinsky, R. A., Wagner, J. K. and Young, R. J., *Leukemia Among Workers Exposed to Benzene,* NIOSH Progress Report, April 26, 1977; McMichael, A. J., Spirtas, M. S., Kupper, L. L., "An Epidemiologic Study of Mortality within a Cohort of Rubber Workers 1964-72," *Journal of Occupational Medicine;* 16, 7, p. 458-464 (1974); Monson, R. R., and Nakano, K. K., "Mortality Among Rubber Workers," *American Journal of Epidemiology* 103, p. 281-296 (1976); and Vigliani, E. C. and Forni, A., "Benzene and Leukemia," *Environmental Research 11,* 122-27 (1976).

now exposed to benzene at levels that exceed the proposed 1 ppm and it broadly discusses the nature of those exposures. The expected lifetime incidence rates of leukemia and the increased incidence rates revealed in the scientific studies [1] can be applied to the benzene-exposed population [2] to derive the number of expected excess cases attributable to that exposure. Varying assumptions about the dose-response relationship should be made to develop an estimate of cases of leukemia which would not occur if the proposed benzene standard is adopted. This last step is necessary because the levels of benzene to which the workers in the scientific studies were exposed were probably substantially higher than existing exposure levels in American industry. The study on which the estimate of a five-fold increase in leukemia incidence was based analyzed a population which experienced exposures from 1940 through the 1960's [3] when common exposure levels were up to 100 ppm (particularly in the 1940's) or up to ten times the current 10 ppm standard. Most of the 191,000 workers to be affected by the proposed benzene standard are exposed to benzene at levels that are currently substantially [9] below 10 ppm.[4]

While the Council does not contend that the above procedures will yield an accurate calculation of incremental benefits, they would provide a range of health benefit estimates that should be included in an economic analysis in order to aid OSHA in setting the final standard. These estimates of incremental benefits should also be developed for each industry covered by the proposed standard. Since current exposure levels in affected industries vary over the range of 0 ppm to 10 ppm and the number of workers exposed varies widely too, the incremental benefits of the proposed standard can be expected to differ between in-

[1] National Cancer Institute, *Third National Cancer Survey: Incidence Data* Monograph 41 (HEW-PHS-NIH: Maryland, March 1975), p. 116-117 and p. 450-451.

[2] *Economic Impact Statement: Benzene,* Chapter 4.

[3] These exposures began in 1940-1949.

[4] *Economic Impact Statement: Benzene,* Chapter 4.

dustries and workplaces. Such a breakdown of expected benefits, together with data on incremental costs of compliance, are necessary to analyze the cost of reducing risk in each industry and are essential in finding the least costly way of doing it.

Analysis of Alternatives

OSHA's economic impact analysis lacks any discussion of the costs and benefits of alternative standards or of alternative means of compliance with the 1 ppm standard.

It appears critical for OSHA to investigate both incremental costs and incremental benefits of more stringent standards as well as less restrictive standards. These estimates are necessary to determine whether a proposed standard should be made even more stringent or perhaps relaxed in some circumstances.

[10] It is even more important that OSHA consider more flexible ways of implementing the standard so that industries and workplaces with differing costs of implementation will be free to use the least cost means of reducing worker exposure. It is in this area that a detailed cost study is most useful to the policymaker since it will identify work areas where more flexibility in accepted means of compliance is warranted. Work areas with very few exposed workers and high costs for engineering controls might be permitted to achieve compliance by using a combination of means including respirators and work practices. These alternative means of compliance may reduce the problem of the $4 billion capital costs of compliance in the gasoline storage and distribution sector noted above.

The proposal does not state an "action level of exposure." [1] Monitoring, medical surveillance, and record-

[1] An "action level"—a concept employed in many other health regulations—is usually one-half the permissible exposure level. If the action level is reached in a workplace, air monitoring and medical surveillance must continue periodically. Otherwise they are not required until a work process has been changed. The purpose of an action level provision is to provide an extra margin of safety and to ensure that workers will not be exposed to dangerous concentrations of toxic substances. At the same time these measures may be avoided when exposures are very low.

keeping must be conducted in all workplaces where benzene is present no matter how small the quantity or the frequency of use. This entails considerable cost with probably little benefit. Therefore the Council urges OSHA to consider adoption of the "action level" approach for benzene. As in other proposed standards containing an action level, an initial determination of exposure levels would indicate whether or not the recordkeeping, air monitoring, and medical surveillance requirements of the standard must [11] be followed. The action level is usually one-half of the permissible level and exposures below it exempt the firm from the other requirements. Process changes involving the hazardous substance call for new exposure measurements.

As the proposal is now drafted, the requirements for periodic measurement, extensive recordkeeping, and quarterly medical examinations apply wherever benzene is present.[1] It would seem that these expenses can be avoided by the use of the action level approach without any reduction of benefits attributable to the standard. Such an approach would also cover all industries where liquids containing benzene are used but it would allow workplaces that use benzene rarely or indirectly and offer no risk of benzene exposure to employees to avoid most of the regulatory costs.

Another alternative that deserves consideration on the basis of costs and benefits is the adoption of a separate safety and health standard for laboratories where many different toxic substances are used. Most laboratories keep benzene on hand since it is a unique solvent that must occasionally be used. However, its use is very limited. The proposal subjects these labs to the extensive requirements of the standard. Even if their use of benzene is extensive, it may be beneficial to adopt an alternative approach under which laboratories would be excluded from this benzene standard and practically all other individual health standards. However, the use of all dangerous substances would be regulated under a single all-

[1] Exceptions exist in the sale, storage and distribution of gasoline and for liquids containing minute amounts of benzene.

inclusive rule that might better [12] take into account (and perhaps require) the unique procedures, equipment and personnel training of a laboratory.

Summary and Conclusion

The economic analysis submitted by OSHA appears to have done a reasonably adequate job of estimating the incremental aggregate costs of the proposed standard but it does not provide adequate estimates of the incremental benefits of reducing the permissible exposure level of benzene from 10 ppm to 1 ppm. Nor has it considered alternative exposure levels and implementation plans. Partly because of its lack of adequate benefits estimation and consideration of alternatives, the analysis has not been adequately integrated into proposal development. The suggested improvements in the analysis can be made in a short time and should help decisionmakers at this stage of rulemaking. The permanent standard should be delayed until this can be done. In the meantime the temporary standard can serve to protect worker health.

We urge OSHA to consider allowing greater use of respirators and work practice controls in areas where exposure is only intermittent and in general to permit the least cost (or most cost-effective) method of compliance to be used. We also urge OSHA to study the costs and benefits of adopting an action level to trigger the costly requirements involving medical surveillance, recordkeeping and monitoring. A separate toxic substance standard for laboratories, geared to their unique conditions, merits some consideration as well.

[Exhibit 115.A-9]

TESTIMONY OF

PROFESSOR RICHARD ZECKHAUSER

BEFORE THE

OCCUPATIONAL SAFETY AND

HEALTH ADMINISTRATION

July 11, 1977

Q. Please tell us your name and present position.

A. My name is Richard Zeckhauser. I am Professor of Political Economy in the Kennedy School of Government, Harvard University. I teach courses in the Law School, Kennedy School and Economics Department at Harvard.

Q. Do you have previous experience in the occupational safety and health field?

A. Yes. I recently completed a comprehensive overview of the Occupational Safety and Health Administration for the Senate Committee on Government Operations. The Senate Committee will be publishing that study later this summer.

Q. Are you an expert on the technological and medical aspects of occupational safety and health?

A. No, I am not.

Q. What is your area of expertise on this issue?

A. I am an economist and policy analyst. My major research involvement at the present time is regulatory issues. I have devoted particular attention to procedures designed to protect and promote human health. I have published a number of professional papers on the life valuation and life protection issue. Two recent publications include: "Where Now for Saving Lives?," with Donald Shepard, *Law and Contemporary Problems*, Fall 1976 and "Procedures for Valuing Lives," *Public Policy*, Vol. XXIII, No. 4, Fall 1975, 419-464. My resume and bibliography are appended to this testimony.

Q. In what way is economics relevant to this subject? Human health, after all, is not a commodity such as those economists usually study.

A. Economics as a discipline is directed to one subject: How should we [2] allocate scarce resources to achieving competing objectives? Virtually every policy field involves competing objectives and scarce resources. Where occupational safety and health is concerned, at the same time that we are attempting to conserve on the expenditure of resources, we are attempting to make the greatest possible contribution to human health.

As part of my testimony here today, I shall be pointing out that only by approaching these difficult policy ques-

tions in a systematic manner can we be assured of achieving the maximum gain in occupational safety and health for whatever level of resource expenditure that we make.

I agree strongly, I should point out, with the argument that human health is not a traditional commodity such as those normally traded on markets. The valuation of lives involves and reflects many of the most basic beliefs and institutions of our society. Given these characteristics, it should not be surprising that some of our decision and allocation mechanisms get tangled. These are the times when the organizing concepts of economics are likely to make their greatest contribution.

Q. Would you suggest that in formulating the proposed standard for benzene and the administrative procedures for implementing it that the Occupational Safety and Health Administration has gotten involved in such a tangle?

A. Yes, I do, though I would prefer to return to that set of issues later after we have had more chance to lay out what I, and what the overwhelming majority of the members of the economics and policy analysis professions, believe to be a sensible and sensitive approach to the problem of protecting human health and lives.

[3] Q. It is sometimes suggested that the economic approach leaves aside a number of considerations that may be important to society when it is involved with programs that save lives. In particular, the question may be raised whether the cost-benefit approach, wherein a price tag is attached to each life lost, has legitimacy in the eyes of decisionmakers and the public. What is your response?

A. First, I think it is important to understand the central lesson of economics is that we should make a conscientious effort to determine what proposed policies will cost us, and what they will achieve for us. The argument against this lesson would have to be that ignorance is better than knowledge. I believe that such an argument would be rejected by the participants on all sides in this hearing. The second lesson of economics is that we should attempt to get our preferences and priorities straight. In the area of health protection, I believe

that there would be little disagreement if we posed as one major objective the effort to achieve maximum health protection for whatever level of resource expenditure that we make. That is, if we are to spend say $5 billion additional dollars in 1980 for occupational health and safety, we should try to organize our programs so that that $5 billion dollars achieves the greatest gains possible. If one allocation would save 5,000 lives and another would save 10,000 lives, then we should prefer the second allocation. (In actual policy making contexts, of course, the problem is more complicated. In particular, it is usually difficult to predict accurately how many individuals will be saved by any particular intervention.)

If we fail to pay careful attention to our priorities in these matters, [4] then we will find that we have achieved less for health and safety than we could have, given our levels of resource expenditure.

I should be explicit. I am not arguing that a cost-benefit approach be employed in formulating policy on occupational safety and health. Such an approach would require that a dollar price tag be attached to a life saved. The value of the lives saved would then be weighed against the resources invested to find the program that offered the highest net value. The major objection to this approach is that there is simply no widely accepted procedure for determining the value of lives in contexts such as these.

Fortunately, there is an alternative approach, called cost-effectiveness analysis, that enables us to establish priorities in programs for saving lives. The guiding principle of cost-effectiveness analysis is that for whatever level of resource expenditure we are undertaking, we should attempt to gain the maximum possible level of effectiveness. The cost-effectiveness technique has been applied in a range of areas where outputs cannot readily be translated into dollar terms, from defense to health policy. The criterion for effectiveness in the occupational health area would be health or lives preserved.

Cost-effectiveness operates by ordering potential policies, starting with those that offer the greatest health gain per dollar expended. These policies are then adopted in

rank order until a particular level of resource expenditure is reached. The level of expenditure may be determined through a preassigned total, perhaps a budget, or it can be the result of some political process. When projects are adopted in this fashion, the highest level of effectiveness will be achieved for whatever level of [5] resources is expended. A critical characteristic of the outcome will be that every project that is adopted will yield a higher level of effectiveness per dollar than any project that is not adopted.

I should like to digress for a moment to make a slightly technical, but highly important point. In conducting cost-effectiveness analysis of programs, or indeed an analysis of any type of program, it is important to determine not only how much is achieved on average for a particular level of expenditure, but how much is achieved at the margin. Let us assume that a proposed program could save an expected 100 lives for an expenditure of $20 million, or $200,000 per life saved. That program might look very attractive in comparison to an alternative that could save lives for $500,000 apiece. But we should also examine the benefits of the first program at lower levels of expenditure. Frequently it is the case that the last measure of protection provided is extremely expensive. For example, in their recent book *Pollution, Prices, and Public Policy* (Brookings Institution, 1975, p. 21), Allen Kneese and Charles Schultze, presently Chairman of the Council of Economic Advisers, note that with pollution control "going from, say, 97 percent to 99 percent removal may cost as much as the entire effort of going from zero to 97 percent." Let us suppose that if the hypothetical program introduced above is cut from $20 million to $10 million, by eliminating its least cost-effective components, the number of expected lives saved will be reduced only from 100 to 95. In that case the marginal cost of saving the last five lives would be $2 million per life. Thus the program should not be operated at the $20 million level until all opportunities to save lives for $1 million each have been exhausted.

[6] This lesson is easily overlooked when occupational health standards are enacted. We might look at a standard that reduces exposure by an amount X at an expenditure of $100 million. The gain may seem worth it. But the gain at the margin may be rather minimal. What if we could achieve a reduction of 99% of X for an expenditure of merely $50 million? Well, that last small reduction in exposure would be costing a very great deal. We still might choose to make the expenditure, but we also might not. The important point is that we should have the marginal effectiveness information available so that we could make an intelligent choice.

Cost-effectiveness analysis starts with a recognition that any government policies directed towards lifesaving involve tradeoffs between resource costs and lives and health. Several years ago, for example, the maximum speed limit was lowered to 55 mph, primarily to conserve fuel. It is generally agreed that the reduced limit also saved several thousand lives. It is clear that we could save even more lives if the speed limit were lowered again, or if the current limit were enforced more strictly. Yet we do not take these steps, I would suggest, because we recognize at least implicitly that there must be a balance between safer highways and the cost of slower speeds, which are measured both in terms of dollars spent on transportation and the time and convenience of automobile travelers. If bodily well-being were the only concern, we would bring all traffic to a halt.

We must recognize as well that any standard that is set for any health hazard implicitly reflects a tradeoff. One thrust of my testimony, and a central tenet of the analytic approach to livesaving, is that it is best to know what that tradeoff might be. As the complete elimination of [7] traffic could eliminate auto fatalities, so too closing down a number of critical industries in the United States could prevent any worker exposure to benzene. We do not wish to pay the shutdown price in either area, so we set the standards to permit some activity, recognizing full well that some threats to health continue. There is no positive level of exposure that we can be deemed 100 percent safe, just as there is no positive speed which eliminates all probability of accident. The level of risk

we accept should reflect the degree of risk we wish to take.

The second principle of cost-effectiveness analysis is that when attempting to accomplish some end such as protecting human health, we should direct economic resources where they accomplish the most. If the expenditure of an additional $1,000,000 would save five lives on the highway, but the same expenditure on plant safety would only save one life, then if we chose the plant safety expenditure over the highway expenditure, we would in effect be sacrificing four lives. The purpose of cost-effectiveness analysis is not to tell us what the tradeoff rate should be between dollars and lives or health, but rather to alert us to the need to rationalize decisions across areas where lives are being saved. If we are to rationalize in this way, we should start by seeing what health accomplishments can be achieved for various levels of expenditure in different areas. Frequently, decisionmakers or governmental agencies concerned with one area will not have responsibility for another. In those circumstances, they may be unable to achieve full consistency of tradeoff rates, that responsibility perhaps belonging to higher level decisionmakers. Still, they would retain responsibility for consistency, hence achievement of maximum health benefits, in their own areas. In the context of the current hearings, this would suggest that though OSHA may with some justification suggest that it cannot be responsible for the consistency of [8] its decisions with those of the Nuclear Regulatory Commission or the National Highway Traffic Safety Administration, it should make every attempt to be consistent across the broad sweep of problems encompassed by occupational health and safety. (The President, OMB and Congress, among others should keep an eye on consistency across agencies.) This principle also applies within the context of a particular standard. Ideally standards should recognize variations in costs across different industries, across firms within the same industry, and even across job categories within different plants.

Q. It is clear that you believe that analysis can play a critical role in assembling information about and making predictions about the consequences of alternative government policies. Could you comment on the possible benefits of more accurate predictions?

A. Yes. I would be glad to. Let me start by remarking on the type of conflict signified by this hearing. It is one of a number of basic debates over how the government should go about promoting health and protecting our lives. Some of these debates may reflect conflicts over values. But I think that they are likely to be in the minority. If we could really make accurate predictions of the consequences of alternative lifesaving and health promoting policies, in terms of both resources and physical well-being, much conflict over those policies would be reduced. The importance of improved prediction is that it helps us resolve debates that can be resolved, in contrast to debates over value questions.

Q. What type of debate do you think is represented by this hearing procedure?

A. Undoubtedly there are some disagreements on value questions. In other instances there may be straightforward struggles over who should benefit in what way and at whose expense. But the substance of the debate, quite clearly, should be over the benefits and costs of various possible standards, including the present permanent standard, the proposed standard, and a [9] variety of alternatives in between. If information of this sort could be presented to this hearing, there would undoubtedly be much wider agreement as to how we should spend resources in the most effective manner to protect workers against the adverse health effects of benzene exposure. This information would consist of answers to such questions as: What health benefits can be expected to be secured from giving medical exams to a particular class of workers four times a year rather than once a year, assuming that spot checks on a small fraction of workers show no unexpected effects? Or what would be the consequence of information loss if expenditures for monitoring programs for benzene exposure were cut by 30 percent below or raised by 30 percent above those in the proposed permanent standard?

Q. You have suggested that one aspect of the predictive effort should be to compute economic costs. What are the economic costs associated with a standard?

A. They are simply the sum total of what all parties have to spend to meet and enforce the standard. Though most of the spending will undoubtedly be undertaken by private companies, the burdens will be shared by consumers, workers and taxpayers at large. If a private corporation is in a 50 percent marginal tax bracket, for example, one half of any reduction in profits due to expenditures entailed by regulations will be borne directly by the taxpaying public as a whole. A further fraction would be borne, or course, given reduced taxes on earnings eventually going to shareholders in the form of dividends or capital gains. Of course, much if not most, of the expenditure will not come out of profits. Some will come out of the wages of workers. More will be passed on in the form of higher prices, in general the less elastic is the demand for the product. For example, since the price elasticity for gasoline is low, additional costs in gasoline production will be mostly absorbed through higher prices.

[10] The economic costs we are talking about represent real resources that could be devoted to other purposes in society. For example, in computing the economic costs of the benzene standard, we should recognize that doctors administering tests for benzene exposure to workers will not be available to deliver other medical services. The workers and machines producing monitoring equipment will be taken away from the production of other equipment that might have been used either to save lives, or to serve any other purpose of society.

Q. But it is well-known that most of the industries affected by this standard are composed of large firms that are profitable. Few firms will close down as the result of this standard. Does that imply that the economic cost is in some way contained?

A. No, it does not. We are still requiring the industries to expend resources that could be used to other purposes. When a company shuts down, there may be additional expenses as resources are shifted to new uses.

These "transition costs" are economic costs over and above those I mentioned earlier, which involve diverting resources from other productive uses. The dollar value of these diverted resources tell us what could have been provided to society if the standard had not been promulgated.

To sum up, there are two important attributes of any proposed standard. They are the health benefits that it can be expected to achieve and the economic costs it can be expected to impose. Thoughtful policy choice would require that careful attempts be made to predict the values of both sets of attributes.

Q. What important predictive information is contained in the Arthur D. Little report that provides an assessment of the proposed permanent standard for benzene exposure? What predictions that should have been made are not contained, and how important are the omitted areas of prediction?

[11] A. First, let me note that, lacking detailed knowledge of the industries and production processes affected by the proposed standard, I have not attempted to evaluate the accuracy of the cost estimates derived by OSHA's contractor. Any such prospective cost estimates, especially when they cut across several different industries, will, of course, be subject to a wide margin of error. Other witnesses, I am sure, are far better qualified to comment on the validity of specific assumptions made about the compliance activities required and their costs.

It is clear, however, that the efforts of OSHA and its contractor, the Arthur D. Little Company, to predict the benefits of the proposed standard have been totally inadequate. It is somewhat startling to read the ADL report—which comprises more than one hundred pages, with an additional two hundred pages of appendices—and discover that the section assessing possible benefits is only eight pages long, three of which are simply a list of references. The studies cited on the effects of benzene exposure are summarized only cursorily. Moreover, the majority of those studies were of workers exposed to benzene at levels far in excess of either the current or the proposed standard, and thus are of little relevance in determining the incremental benefits of the tighter exposure limit.

In discussing the benefits of the proposed standard, the ADL report refers rather vaguely to "reductions in leukemia potential, blood abnormalities, and general occupational morbidity . . . a better informed workforce . . . [and] . . . an increase in the body of knowledge related to all facilities utilizing benzene . . ." (p. 3-5). Neither the ADL report nor OSHA's discussion in the *Federal Register* make any attempt to quantify the health benefits of moving from the present standard to the proposed one. Let me stress again that by "quantify" I do not mean that the potential benefits need or even [12] should be expressed in terms of dollars. Rather, I mean that OSHA has provided no estimates of the number of lives to be saved or cases of illness to be avoided by the imposition of this standard. While I appreciate the fact that the limited data available make it impossible, as the ADL study suggests (p. 3-5), to specify "benzene's precise dose-response relationship," it is also impossible to evaluate the standard in any meaningful way without some estimate, however crude, of its benefits. Even if such an estimate could not be refined beyond a broad range of possible effects, it would be of immense value. From the documents I have seen, we have no idea whether the proposed standard would save no lives, ten lives, or 1000 lives for an annual expenditure of more than $100 million. At the very least, OSHA should present a range of estimates of the health losses due to current levels of exposure to benzene. With such estimates it would be possible to place an upper bound on the incremental gains of the proposed standard, as OSHA admits that it will not eliminate all health effects.

Q. What sort of analytic capability exists within OSHA that would have enabled the agency to make good use of predictions had they been provided?

A. Unfortunately, OSHA has made little effort in the policy analysis area. This has not been a priority of the agency in the past, and although a small policy analysis operation was begun in 1976, it has hardly achieved a central role within the agency. In the review of OSHA that Albert Nichols and I conducted for the Senate Committee on Government Operations, we concluded that:

"OSHA should establish as a top priority the development of a policy analysis capability that would enable the Agency to formulate concrete objectives, detail performance on those objectives, evaluate alternative approaches to governmental promotion of health and safety, and develop long run plans for OSHA." Until a strong policy analysis staff is put [13] in place, it seems highly unlikely that OSHA will be able to make use of either the type of analysis that Arthur D. Little prepared in assessing this standard, or the type of analysis that I have suggested should have been prepared.

Q. How could these predictions of the type you request deal with the fact that our scientific understanding of these issues is not complete, our data base is limited, and we do not really know from experience what benefits can be expected?

A. Your question merely reflects the facts that we are making a regulatory decision under conditions of great uncertainty. That is frequently the state of affairs. The more significant the uncertainties, usually, the greater are the benefits for some sustained study of the problem. If initial predictions of health benefits range, say, over two orders of magnitude, several months of investigation may narrow the predictions to within a factor of ten. Extreme narrowing of this sort may dramatically change both the form and severity of the regulatory intervention that we wish to employ in a particular case.

I should point out that there is the academic discipline of decision analysis that has been developed to deal with situations of considerable uncertainty. There are a number of primary lessons drawn from that discipline that would seem to be relevant to any attempt to set standards and procedures relating to benzene exposure. Let me cite three. 1) Make careful attempts to estimate the values of critical variables, specifying a range of uncertainty when appropriate. 2) Make conscientious efforts to estimate the value that new information would bring in terms of an improved decision; develop, assemble, and process information when its expected value exceeds the cost of producing it. 3) Where uncertainties persist, employ a sequential strategy, where future actions will be

[14] influenced by information gained along the way. There is no evidence that any of these lessons has been considered, much less applied, in formulating the proposed permanent standard for benzene exposure.

Q. There are many specific aspects of the proposed permanent standard relating to requirements across industries and job categories, the role of personal protective equipment, exposure measurements, medical test requirements, and the like. Can you comment on the overall structure of this approach?

A. Let me deal first with the question of variations across industries and job categories. The principle of cost-effectiveness states that the marginal cost of achieving a given increment of protection should be constant across industries and job categories. If it is not, we could achieve greater protection at the same cost by relaxing the standard where marginal costs are high and tightening it where they are low. OSHA has taken some cognizance of this principle by exempting certain types of firms, specifically those using benzene only at very low concentrations and those distributing and selling gasoline at the retail level. It has not, however, analyzed differences in marginal costs across the affected industries and across different job categories within each industry.

The proposed standard continues OSHA's general policy of opposing the use of personal protective equipment, in this case respirators, except in certain extreme cases. OSHA's primary argument is that respirators are not always properly fitted and often are not used by workers. However, in many instances it is likely that respirators offer a relatively low-cost alternative to engineering controls and should be permitted, even if engineering controls are "feasible" in a purely technical sense. Moreover, engineering and work practice controls hardly offer foolproof protection. Controls may be installed but not used or maintained properly. Workers may not obey the work practice rules set up by employers. Firms [15] should be permitted maximum flexibility in meeting whatever exposure limit is set. If firms choose to use respirators and workers find them uncomfortable or inconvenient, then certainly it would be appropriate for labor and

management to negotiate over the mix of engineering controls, work practice rules, and respirators used to meet the exposure limit.

On the issue of exposure measurements and medical test requirements, I am not qualified to comment on the technical aspects, such as what tests should be used, or what the appropriate interval is between tests. However, I find it rather remarkable that the costs of medical surveillance and exposure measurement each make up one third of the estimated first-year costs of compliance. Most of these costs will be incurred in workplaces where workers even now are not exposed to benzene at levels in excess of 1 ppm. It strikes me as being highly improbable that frequent medical surveillance is as necessary in low-exposure workplaces as in those above the limit. Reducing the frequency of testing could effect large savings, quite possibly at little or no loss in worker protection. The same may be said of exposure measurements as well, although OSHA has provided for less frequent measurements in workplaces found to be below 1 ppm. Given the very high costs of both surveillance and exposure measurements, considerably more analysis needs to be done on the question of how often different types of workers need to be tested and their exposures measured.

Q. What is your summary view of the proposed permanent standard on exposure to benzene and the analysis that was conducted by Arthur D. Little to support it?

A. First, it seems evident that no underlying principle was employed to establish the standard. I have suggested that cost-effectiveness analysis [16] does provide such a principle. It requires quite simply that we make our expenditures on occupational safety and health where they can be seen to yield the greatest benefit.

The analysis in support of the standard was highly inadequate in that it made virtually no attempt to measure the health benefits that the standard would produce. Obviously, there was no attempt to compute marginal benefits and costs associated with alternative standards. Those marginal quantities are the ones that should be focused upon in making any policy decision.

The form of the standard and the particular testing, evaluation, and monitoring procedures it requires suggests that little attempt has been made to limit resource expenditures where they can be expected to yield little health benefit, if any. Even the simple principles of sampling theory and elementary statistics seem to have been left aside in the design of the standard.

Q. What action would you recommend be taken on the permanent standard?

A. It would be inappropriate to take any action—be it adopt, reject, or modify—without the information that would be required to make a sensible decision. I would strongly urge that analyses be commissioned to compute the marginal benefits and marginal costs of the major aspects of the standard. Given such information intelligent decision making can proceed. In the absence of such information, no decision could reflect more than an emotional or political response to an uncharted situation. Much is at stake in the establishment of a permanent standard on benzene exposure. Intelligent decision making should be given a chance.

[Exhibit 115.C-1]

TESTIMONY OF DR. HOWARD I. MAIBACH

BEFORE THE

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

July 11, 1977

My name is Howard Maibach, M.D. I received my A.B. in 1950 and my M.D. in 1955 at Tulane University, New Orleans, Louisiana. My internship at the William Beaumont Army Hospital, El Paso, Texas (1955-56) was followed by two years of military service—initially at Walter Reed Army Hospital, Washington, D.C. and then at the 42nd Field Hospital in Verdum, France, where I was in charge of neurology, psychiatry and dermatology. Completing military service I matriculated at the University of Pennsylvania in Philadelphia, Pennsylvania for clinical and research training in dermatology from 1958 through November 1961. I joined the staff of the University of California Medical Center, San Francisco, California as an Assistant Professor in 1961; I remained and am presently Professor of Dermatology.

My research interests concern the biology of the skin and, most specifically in regard to this testimony, the effects of the chemical environment on the skin. I authored or co-authored approximately 300 papers and edited 5 books.

My curriculum vitae and bibliography are attached (Maibach Exhibit 1).

This bibliography covers a broad range of cutaneaus research; several specifically concerning the effects of chemicals on the skin. Most directly, publications from 1965 to the present document the penetration of chemicals through the skins of animals and man, and the relevance of animal models to man.

[2] I reviewed the information supplied by counsel for API and NPRA that has been cited by the Occupational Safety and Health Administration ("OSHA") proposed prohibition of skin contact with benzene to determine whether it provides an adequate basis for rulemaking in this area. These include: Hanke, J. T., Dutkiewica, and I. Piotrawski: (The absorption of benzene through the skin in men.) Med. Pracy 12:413-26, 1961 (OSHA Doc. No. 69); Cesaro, A. N.: (Is absorption of benzene through the skin possible?) Med. Savoro 37:151-156, 1946 (Ital.) (OSHA Doc. 47); and Dutkiewicz, T., H. Tyras: A study

of the skin absorption of ethylbenzene in man. Br. J. Indust. Med. 24:330-32, 1967 (OSHA Doc. 123).

My comments relate solely to the state or the science and art of quantitating percutaneous penetration. I have not reviewed the entire issue of benzene toxicity as this relates to prohibition of use or level setting.

In discussing the relevance of percutaneous penetration to a biological effect in either animal or man, the observed biological or clinical effect involves how much of the material penetrates the skin and what is the biological effect of that material when it enters the body. Chemicals severely toxic when injected into animals in small amounts may be safe for man if this does not penetrate. Conversely, chemicals with moderate animal toxicity can produce toxicity in man if large amounts [3] penetrate. Thus, in extrapolations of what is likely to be observed in man, one needs the kinetics and total penetration and the biological potential of that penetrant. The question at hand is how much benzene is absorbed through the skin? The most pertinent data at the present is: Hanke, Dutkiewicz and Piotrowski, Institute of Industrial Toxicology of the Institute of Labor Health, Lodz, Poland, Absorption of Benzene Through the Skin (Med. Pracy 12:413-26, 1961). These authors summarized the literature to 1961 and added experimental data.

The first reference is Lazarev, Brussiolovskay and Larov (1931), who conducted tests on rabbits and mice. Contact with liquid benzene was accomplished by immersion of the animal's ear or paw in the liquid benzene for several hours. We have no experimental data permitting extrapolation of this type of prolonged immersion experimentation to casual contact in man, nor do we know how to extrapolate data from the rabbit or mouse ear or paw to man.

It is known through studies of several materials, not including benzene, that rabbit skin is many-fold more permeable than human skin. (Bartek, M., LaBudde J. and Maibach, H.): Animal model for percutaneous absorption, Chapter 13 in Animal Models in Dermatology, Churchill Livingstone, London, 1975 (Maibach, H. ed.) (Maibach Exhibit 2).

Furthermore, any extrapolation from these animals' ears or paws being immersed for many hours to man must be made with [4] great caution. Lazarev *et al.* determined that the absorption rate was approximately 3 milligrams per square centimeter per hour. Although this could hold true for man, we do not at the present have studies comparing the two species to allow us to make this extrapolation.

In the Lazarev study the skin was "mummified" by benzene exposure. Presumably this means markedly damaged skin not comparable to that of the normal worker dealing with benzene.

Cesaro (Med. Lavoro 37:151-6, 1946) placed adult males nude in a metal tank for 20-30 minutes. Their skin was exposed to unspecified amounts of benzene vapor and liquid. Utilizing an inorganic sulfate—total sulfate method, he examined the subjects urine to determine if penetration occurred. He sought benzene in their expired air with an apparatus consisting of a mechanism to bubble the breath through a formalin solution in concentrated sulfuric acid. Benzene, if present would produce a brown color.

In neither experimental circumstance did he observe data suggestive of percutaneous penetration.

This negative data must be interpreted with caution; neither assay had sufficient control data to permit an estimate of sensitivity; i.e., what is the minimum detectable level?

Teisinger and Fiserova-Bergerova (1955) quantitated the percutaneous penetration of benzene by measuring the amount of phenol in the urine of man. Hanke et al. believed that this was [5] a sensitive method and, thus, utilized it in their studies. Comments as to its sensitivity follow.

In the Hanke et al. study, benzene (0.02 ml) was applied by microsyringe to a watch crystal pressed to the forearm with an elastic. "The glass is placed under a funnel having a slightly larger diameter which, with the aid of a short elastic connecting piece, [was] connected to a water suction pump through a rinsing machine with a porous glass containing 20 ml of nitrating mixture

(10% ammonium nitrate in concentrated sulfuric acid) as an absorbing solution."

It is not clear if the watch glass was used as an occlusive dressing. If it was we believe that penetration would be ten-fold higher due to occlusion (when comparing this to the usual nonocclusive application of benzene to human skin). For most studies published to date, occlusion increases penetration approximately 10-fold. Feldmann and Maibach, published studies, and Feldmann and Maibach, unpublished studies (Maibach Exhibit 3). This occlusion enhancement has been documented for hydrocortisone, testocterone and several pesticides. Although it is possible that some workers do occlude their skin when contacting benzene, these figures resulting from occlusion must be separated from those without occlusion.

In addition to measuring the urinary excretion of phenol, Hanke et al. trapped benzene coming through into the funnel.

They performed 52 tests of the concentration of phenol in [6] urine, finding an average of 7.2 milligrams per liter of phenol in urine in subjects not known to be exposed to benzene. This was the baseline observation to which their subsequent data relates. Expressed in milligrams per hour this is 0.2 percent per hour.

They exposed volunteers' forearms. They state that "a plate with benzene saturated cotton was placed on the forearm" with a dose of about 0.06 grams per centimeter square. "This plate was insulated with the aid of cellophane affixed to the forearm with adhesive tape. The contact area was 35 to 45 centimeters square and the contact time 1.25 to 2 hours." This suggests this exposure was occlusive; the importance of this relates to the previous comment as to the effect of occlusion on percutaneous penetration in man (increasing this by approximately ten-fold). Note also the prolonged contact time (1.25 to 2 hours), which is longer than casual contact.

"The urine samples were taken for an entire day, every 1 to 3 hours, and less often at night." It appears that they did not have a complete urine collection.

The data for the five subjects was reported as the maximum concentration in milligrams per liter and the

rate of excretion in milligrams per hour. For example, the maximum concentration, which they termed physiologic excretion—for non-exposed subjects, was 16.0 mg/1 while the level for exposed subjects were as follows: 15.8, 17.0, 28.3, 22.1 and 16.9. Thus, of the five subjects, 2 were above baseline and 3 were essentially similar to baseline.

[7] Physiologic (baseline) excretion was listed as 0.57 milligrams per hour whereas excretion in exposed persons was 0.79, 1.7, 0.96, 1.9 and 0.75. Again, two of the subjects were significantly higher than the remainder.

Unfortunately, they do not have baseline data on each subject so that each subject could act as his own control; this would help determine whether these were subjects who had been exposed to any phenolic material that would be excreted as phenol. The authors do not appear to eliminate the possibility that these two subjects represented contamination from another source.

There is inadequate kinetic data present that would allow us to ascertain that, after exposure, levels went up and then decreased in a meaningful way. The data given in Figure 5 documents the extensive variation of phenol excretion in a non-exposed subject.

Making these calculations, they concluded that, under these particular methods of exposure and using this method of determining benzene penetration (phenol in urine), the average rate of absorption was 0.24 milligrams per centimeter per hour. They cautioned that "in view of the number of assumptions made in the course of calculation, this value should be taken only as a reference value."

The authors caution "it should be noted that the results pertaining to the rate of absorption of liquid benzene through the skin refers to the extreme case, where the skin of the exposed [8] individual is *completely damped by benzene at the point of contact;* these are thus maximum values." If this means that the watch glass was in fact occlusive these factors are at least ten-fold more than would be seen in casual exposure (without occlusion or soaking).

Since benzene is highly volatile, if the rate of volatility was greater than the rate of absorption, this would greatly alter the amount penetrating when there was no occlusion present. In this instance, the ten-fold enhancement with occlusion may be an underestimate of the total enhancement factor.

Hanke placed three nude subjects with both water hydrated skin in a chamber exposing them to benzene vapors at 1.0 mg/liter (air temp, 25°C and humidity, 35%). Utilizing urinary phenol excretion as an index of penetration, no increase was noted, after 1.5 hours exposure. With seven hour exposure, they noticed an increase of phenol excretion of 2.7 and 4.2 respectively. They state: "If we consider that at the same concentration of benzene in the air (1 mg/liter) and pulmonary ventilation of about 3 m^3/7 hours, the amount of absorption through the lungs would be about 1500 mg."

Comment:

In summary, there are many incomplete facts in the available data making it extremely difficult to extrapolate to make any relevant decision for man in 1977 based on knowledge of the actual amount of benzene absorbed from normal skin in casual contact. [9] To improve the situation we need the following: (1) percutaneous penetration data performed with a technique that is likely to ascertain if the material absorbed is or is not benzene or one of its metabolites. At the present, the most effective way to do this would be to use carbon 14 labeled benzene.

To verify that absorbed benzene or metabolite can be monitored, a tracer amount of benzene should be injected into the animal (or man) to verify that completeness of recovery has been obtained in either urine or feces. If the material is expired in air, or if the material is stored in a body site, the errors utilizing urinary excretion may be considerable. If the entire parenteral dose can be accounted for by this process, it can be assumed that the estimates of absorption through skin are likely to be accurate.

(2) It is important to determine what the half life of excretion is once the material is absorbed. This will help determine who long urine and/or stool should be studied after a single dose. This calculation can be made simply on the basis of the parenteral control.

(3) Hanke et al. assume that the fate of benzene from skin exposure involves a given percentage being metabolized to phenol. This is probably the case, but additional experiments should be sought to document this. Until this is documented, one must *not* assume that the fate of benzene via the lungs is the same as the fate of benzene via skin contact. There are [10] several examples in which the metabolism from parenteral and cutaneous exposure has been compared and in which there has been significant differences between the two. E.g., corticosteroids (Mavis, Greaves, J. Invest. Derm.) (Maibach Exhibit 4).

(4) We should know the effect of a variety of concentrations on the skin. For some compounds there is a linear dose relationship: the more it is applied, the more it goes through. Ref. Wester, R. and Maibach, H., J. Invest. Derm. 1976. This does not hold for all chemicals. The only way to know this for benzene is to do the experiment.

(5) We do not know if multiple applications will produce more penetration than single applications. It is ordinarily assumed that each time you apply the material, more of it is being absorbed: recent studies with two chemicals show that this is not always the case. Wester, Noonan and Maibach, Frequency of Application of Percutaneous Absorption of Hydrocortisone, Archives Derm. 113:620, May 1977 (Maibach Exhibit 5).

(6) We should know the effect of splashing of the material on skin compared to soaking on skin. With splashing, it is possible that the material may evaporate too rapidly to penetrate; this might be different than that absorbed from a dressing or in an occlusive cutaneous exposure such as noted in these studies.

Obtaining this data should be relatively straightforward with the availability of carbon 14 labeled benzene. If it is deemed necessary to do this first in an animal, the

rhesus [11] monkey is the animal that has the greatest amount of background data comparing permeability to that of man. The comparative studies are summarized by Wester, R. and Maibach, H.: Penetration in Animal & Man in Cutaneous Toxicity, 1977 (Drill, V. ed.) (Maibach Exhibit 6).

The amount of time required to obtain additional data would be six to eight weeks; an extensive profile of penetration could be obtained in 12 to 24 weeks. Similar studies could be safely done in man because the chemical and radiologic exposures are extremely small.

[Exhibit 149.B]

DIRECT TESTIMONY OF RICHARD WILSON

Experience

1. My name is Richard Wilson. I live at 15 Bracebridge Road, Newton Centre, Massachusetts and I work as a Professor of Physics at Harvard University. I obtained my B.A. in Physics at Oxford in 1946 and my M.A. and D. Phil. in 1949. I have done research and taught at several institutions since then.

2. My principal research has been in nuclear and elementary particle physics.

3. In the last six (6) years, I have become interested in the environmental and public health hazards of energy systems. I have taught a course in this at Harvard and am acting Director of the Energy and Environment Policy Center at Harvard. This has led to my making comparative analyses of many hazards in life.

4. Recently I have been a consultant on reactor safety to the State of Maine, and also a consultant to the Energy Research and Development Administration, the Nuclear Regulatory Commission. I am studying safety of liquified natural gas facilities for the General Accounting Office.

5. I have worked with radiation all my professional life and have become aware of the risks and dangers of radiation—from x-rays as well as from radioactive materials. I am Chairman of an interfaculty committee at Harvard which runs the Harvard University cyclotron, built originally for physics research and with which I did nuclear physics experiments, but now used for medical treatment of various tumors—both proliferating and non-proliferating. In this capacity I work with the head of the radiation medicine department at Massachusetts General Hospital (who is a member of the committee) and some of his staff. My knowledge of the effects of low levels of radiation is accepted by them, and I have lectured to the interns and residents on this subject. Thus, I am well aware professionally of the problems of

cancer. I am also well aware on a personal basis since my stepmother died of cancer 15 years ago and my father died two months ago—both probably attributable to tobacco smoking.

6. I have twice testified on safety at the Joint Committee on Atomic Energy of the U.S. Congress; I have testified on risk/benefit analysis at a Subcommittee of the Committee of Science & Astronautics of the U.S. House of Representatives; I was asked by the Food & Drug Administration to comment on the proposed saccharin ban and have testified at an FDA hearing. I have lectured on risk/benefit analysis at energy symposia, an American Chemical Society meeting, and at a special Risk/Benefit Conference at Asiloma, California.

Introduction

7. I wish to testify about the level of risk that may conservatively be associated with the use of benzene in its occupational setting and, hopefully, put this risk into some perspective with a number of other risks that society has prudently chosen to ignore or accept. I have not personally done the experimental work which produces the numbers which go into the analysis, but I have reviewed the documents presented, and others to which I will refer. I have paid particular attention, of course, to those areas where the Occupational Safety and Health Administration (OSHA) and the Manufacturing Chemists Association (MCA) appear to disagree. I will outline the logic of this analysis, and try to highlight for you those places where assumptions are made. In such analysis there are places where good data do not exist, and we hope never will exist (we have not deliberately given one million American workers large doses of benzene to find their sensitivity directly); therefore, the evidence must of necessity be imprecise. Nonetheless, there is a logical procedure, which can demonstrate with conservative assumptions that an average level of benzene in the workplace of 10 ppm is much more acceptable than many other actions.

8. I wish to make it clear that *before* agreeing to testify, I satisfied myself that the benefits attributable to the manufacture of benzene with a 10 ppm level outweigh the potential risks associated therewith. The purpose of this testimony is to present an estimate of the occupational risk in terms which permit a comparison to other risks which society regards as insignificant.

[Figure 1 Omitted in Printing]

The Problem

9. The scourge of cancer afflicts one quarter of all Americans in their lifetime, and 18% of Americans eventually die from the disease. Massive efforts have been made to discover the causes of cancer and to effect a cure. About $25,000 per patient is spent trying to cure cancer.

10. In the last year, there have been several reassessments of the direction of this attack. For example, the prestigious public interest lobbying organization, the Federation of American Scientists, has summarized a part of the issue in a recent public interest report (May 1976). In the last 15 years, there has been very little improvement in the cure rate for cancer. This is shown dramatically in Figure 1 where the survival rate has been only slightly improved.

11. The trends in cancer mortality rates are shown in Figure 2. These are adjusted by age. This is necessary, because cancer afflicts old people more than young people, and as other causes of death are removed from our society, a larger proportion will die of cancer. This age adjustment removes much of the pragmatic rise in cancer over the last few years. But for some cancers, mortality *has* dramatically increased.

[Figure 2 Omitted in Printing]

12. Attempts to find a universal cancer virus which causes cancer have so far failed. If a virus were found, a vaccine against cancer would be possible. Therefore, a vaccine against cancer does not seem likely in the near future. Accordingly, society is left with two immediate choices—accept cancer and try to cure it by surgery,

radiation or chemotherapy, or try to remove the causes of cancer.

13. It has been widely stated that between 80% and 90% of all cancers are of environmental origin. The word environment must be used in its broadest sense. Although the evidence either way is not definitive, most cancers do not seem to be caused by genetic defects passed on by the previous generation or by a contagious virus. If this is true, they can only be caused by man's environment: the air we breathe, the food we eat, the tobacco we smoke, and the radiation we receive. Moreover, as outlined by Sir Richard Doll, there is also positive evidence that environmental effects are important. Japanese have a lower incidence of cancer of the digestive tract than Americans; but when Japanese move to America, they develop American habits and get the American incidence.

14. At this point, I feel it is important to provide some perspective for the term "environmental origin." A recent editorial in the *Journal of the National Cancer Institute* by Drs. Ernst L. Wynder and Gio. B. Gori (Attachment I) provides a thorough evaluation of the significance of the environmental origin finding. The basic conclusion of the article with which I fully agree is that lifestyle factors such as cigarette smoking, alcohol consumption and improper diet are the prime causes of "environmental cancer" and that food additives, air and water pollution, and toxic chemicals in the workplace are relatively minor contributing factors to the world's cancer problem.

15. The significance of lifestyle factors is not the least surprising when one considers that the 90 percent "environmental cancer" estimate was derived by comparing cancer rates from around the world and attributing any excess cancer mortality above the lowest rate found anywhere in the world for a particular cancer to environmental factors.

16. There is, as yet, no big upsurge in cancer. But two facts urge society to be cautious. The biggest increase in cancers, as shown in Figure 2, has been in lung cancer. These are now almost all attributed to cigarette

smoking. The increase in men followed by 30 years an upsurge in cigarette smoking by men in the 1920's, and the increase in women is just beginning—again following by 30 years a postwar upsurge in cigarette smoking by women. No other types of cancer have shown such dramatic increases, and no other is responsible for such a large number of cases. Although cancer of the colon has been attributed to the diet of the Western World, there is debate on what the actual cause is; some people argue that Westerners eat too much meat, others that they eat too little fibrous cereals. In any event, mortality from such cancers has shown a slight decline over the last thirty years.

17. Since the Second World War there has been a massive increase in the use of industrial chemicals—many of which do not exist in nature. This suggests that society should exercise caution because if some of these chemicals are carcinogenic, we may get an increase of cancer comparable to that caused by cigarette smoking, but delayed by some period of latency. After the first cases have appeared, it is too late to prevent most of the later ones. But we should remember that benezne has been used for over 50 years, and at concentrations far exceeding these presently allowed, so that this general argument does not apply in this case. The issue in this case is not whether one should exercise caution, but how much caution; excessive caution can prevent otherwise desirable actions.

ESTIMATING THE RISK ASSOCIATED WITH EXTREMELY SMALL DOSES

Tests on Humans

18. One possible way of measuring cancer incidence or toxic effects is to try the chemical out on 1,000,000 American workers, and if there is trouble, correct it. For obvious reasons, this is not acceptable. If we started exposing Americans to an unknown chemical, we might be inducing a lot of cancers and not know for 20 years; then society might be unwilling to stop as in the case

of cigarettes. Even if we stopped, the cancers would keep on coming because of past doses.

19. Of course, if for any reason a mistake has been made in the past and some people have inadvertently been exposed to a carcinogen at a high concentration, we must study its consequences so that we may learn for the future. Much of our present knowledge of cancer comes from such mistakes: cigarette smoking, radiation cancers (mistakes of medical men for the most part, but also Hiroshima and Nagasaki), asbestos occupational cancers, and vinyl chloride occupational cancers. Now, we want to assess the risk associated with the production of a chemical in the workplace.

Tests on Laboratory Animals

20. The most practicable method for determining carcinogenesis is to test it on animals. We use *mammals* with a short reproductive cycle—mice and rats. In their lifetime these are believed to approximate man with a longer lifetime in their genetic mutations and cancer incidence. This method has been verified for some cancers where, due to human error, human data exists. Smoking and radiation (from Hiroshima, Nagasaki, and incorrect use of X-rays) and vinyl chloride are examples. Even if we accept the idea that one species is a surrogate for another, we still have a problem. We want to test a chemical suitable for use by 1,000,000 people. If we are to test at the dose level which we are interested in using, and want to be sure that not more than one person gets a cancer in a generation, we need far more than 1,000,000 rats or mice. Typical mice experiments use only 100 mice in attempting to establish the absence of a cancer threat for 1 million people. Obviously, using a larger number of mice would strengthen the assurance obtained from such tests; however, the presence of background cancers due to other causes makes the use of even 1,000,000 mice too few to reduce the risk of cancer in a generation of 1,000,000 people to zero.

21. One solution is to test with mice at a higher level than that at which man might be exposed and find

some way of interpolating the result down to low dose levels that correspond to practical application. Interpolation procedures have been aired very much in the public press in the last three months as a result of the Food and Drug Administration's proposed ban on saccharin as a food additive. The extrapolation of animal data to man has been the subject of two rule making documents published in the *Federal Register* in the past 4 months. The interpolation procedure and the extrapolation from animal to man are major uncertainties.

The Dose-Effect Relationship

22. There are several possible procedures for interpolation between the measured points at high doses, and zero effect at zero dose: the prime requirement of any such interpolation is that it gives a conservative estimate of the risk associated with a given dose level.

23. The conservative extrapolation procedure I use is the linear method. In this method it is assumed that a direct proportionality exists between the size of the dose and the incidence of cancer. Other witnesses will testify that there is a threshold for most carcinogens, below which there is no carcinogenic effect. I neither accept nor deny this assertion but merely state that the assumption is unnecessary to establish acceptability.

Risk is a Function of Average Concentration Over a Long Time

24. If we assume that a linear plot is correct, then the only way to obtain zero risk is if there is zero dose. At extremely low doses, however, the risk may be so extremely small as to be insignificant, and hence, should be acceptable. The first step to approximating this risk is to obtain an estimate of the appropriate dose for basing the risk extrapolation.

25. At this point it may be useful to outline the crucial parts of the Armitage-Doll [1] multilinear theory of

[1] P. Armitage and R. Doll., "The Age Distribution of Cancer and a Multi-Stage Theory of Carcinogenesis," *British Journal of Cancer*, Volume VIII, No. 1, Page 1 (1974). (Attachment II).

cancer incidence. This is a theory of cancer incidence at the level of a cell derived from the age distribution of cancer in human populations. A theory based on mechanisms for formation of the disease would be preferable, but we know too little about cancer for such a treatment. Nonetheless, advances in numerical work in the last 20 years, particularly by Sir Richard Doll, now Regius Professor of Medicine at Oxford, have improved our understanding a lot. It is an important part of the improvement in understanding that we no longer talk about whether a chemical is a carcinogen or not, but what is its carcinogenic potency.

26. It is assumed necessary for a cell to receive $k + 1$ mutations before a cancer occurs. Each mutation is caused by some insult, the probability of which is proportional to time and to the concentration of the substance causing the insult. If people are exposed all their lives this leads at once to the formula for the probability of getting a cancer at the lifetime, t, and in the time dt.

$$dN/N = (p_1 t)\,(p_2 t) \ldots (p_k t)\,(p_{k+1} dt)$$

Then the rate of increase of the population due to cancer is

$$\frac{1}{N}\frac{dN}{dt} = \lambda t^k$$

Experimentally $2 < k < 8$ and depends upon the site of the cancer, and not on the environment; λ depends upon the environment. I have derived this formula from a theory. In fact, this formula is a fit to the observed cancer incidence. Armitage-Doll derive the theory from the formula.

27. Although this theory assumes a *particular* mechanism, the same formula can be obtained from several mechanisms. However, they have in common several features which are generally experimentally correct.

(a) There is a latent period between an individual insult and the cancer observed.

(b) A synergism is predicted whereby cancer incidence can be proportional to the product of the concentration of 2 substances—this has been observed for radiation and smoking, for asbestos and smoking.

(c) If an individual substance causes only one of the insults, then the cancer incidence is linear with the concentration of that substance as often observed.

I do not wish to go into detail about these theories, but I do want to emphasize that inherent in models of this type, particularly those which assume linearity, is that the *parameter which matters is the concentration of the substance averaged over a long time—an appreciable fraction of a lifetime.*

28. As noted above, there are repair mechanisms which may make the cancer incidence less than linear at low doses and at low dose rates (see Appendix A). Accordingly, the pessimistic linear theory shows that taking the concentration averaged over a long time is pessimistic also. This fact, however, enables us to calculate a risk using simple arithmetic; if this risk is low; there is no need to go further and ask whether this pessimism can be removed by a more complicated calculation.

Mutagenicity

29. Meselson [2] has shown that one can in many cases obtain a *quantitative* correlation of mutagenicity with carcinogenicity. This is consistent with the idea that both mutagenesis and carcinogenesis are a function of the change of a DNA molecule. This linear relationship would be expected if pure strains of bacteria and pure strains of animals, without repair mechanisms, are used. Although there are carcinogens which are not mutagens, this is not expected for organic compounds provided that yeast or liver extract is used to mimic the metabolic behavior of the human liver and gut, and mutagenicity will in most cases tell us about carcinogenicity, since there are no repair mechanisms.

With this background, it is appropriate to look at the data. There are three sets.

(a) As of June 27, 1977 [3] no mutagenesis has been observed. The background is about 100 revertants per

[2] M. Meselson and K. Russell paper appended as Attachment III.

[3] Personal communication from Dr. Ames' group at the University of California at Berkeley.

plate and no mutagenesis is observed with quantities of benzene up to 100 μg in the strain TA 100 both with and without liver extract to provide metabolities. This suggests that benzene is at most a weak mutagen, 10,000 times weaker than aflotoxin as shown in the graph from Meselson's paper. (See Figure 3).

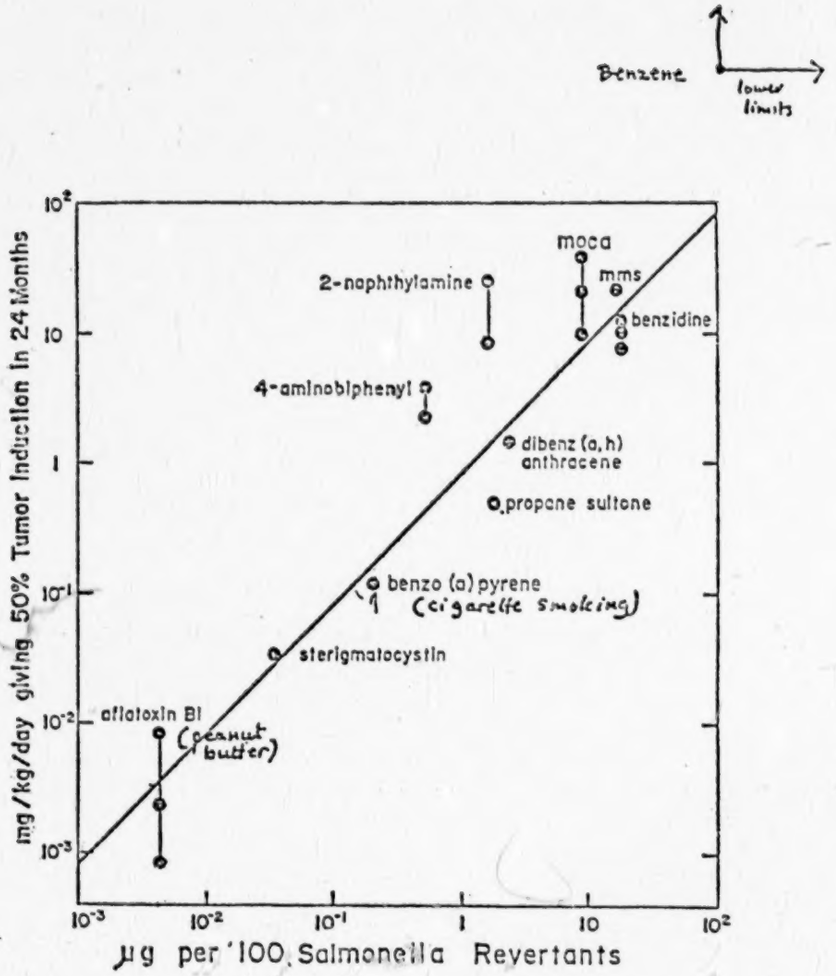

Figure 3
from Meselson

(b) There have been several animal experiments in which attempts have been made to find leukemia induced in mice or rats. These have been primarily by a limited number of sub-cutaneous injections.[4] In one experiment leukemia appeared to have been induced in mice but despite some attempts, that experiment has not been duplicated. None seem to have been by lifetime inhalation studies.

(c) Clinical and epidemiological studies.

These are by Aksoy, Vigliani, Thorpe and Infante.[5] They are inconsistent. I have plotted them in the attached graph in Figure 4. I note that according to our ideas, at this low incidence of leukemia, the incidence should be proportional to dose, or less than this at the lowest dose.

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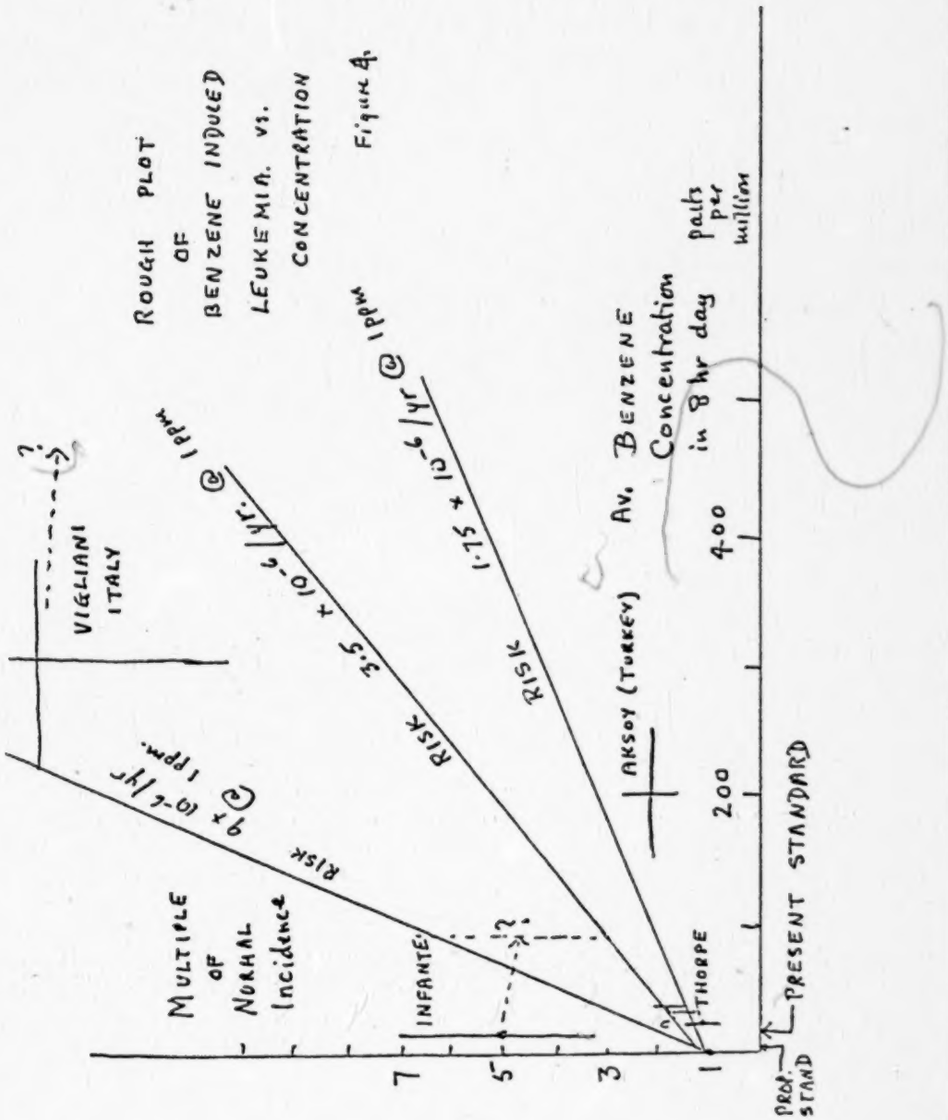
[4] Experiments listed in the *Federal Register* 42, 103 27470 May 27, 1977.

[5] Federal Register 42, 103, 27468 May 27, 1977.



Others may comment in detail on the Infante study. I note here, however, that if the numbers of patients and dose are taken seriously, then there should be a fifty fold increased incidence of leukemia among Turkey's shoemakers, (Aksoy's study) which could not have been missed. There are many questions to be asked about the Infante Study.

Accordingly, I believe that the Infante data cannot yet be taken literally, but I take a figure for leukemia of 1.8×10^{-6} yearly risk at 1 part per million concentration averaged over an 8-hour working day. This is derived from the line drawn on the graph by noting that the normal leukemia incidence in the USA is 15,000 per year (5% of all cancers and 0.75% of all deaths) and that the benzene exposure will increase leukemia not only among the workers, but this increase will continue until old age in spite of retirement! This may be too pessimistic by a factor of 3, since the deaths *expected* by Infante are 0.3%.

I conservatively assume for every leukemia there is one additional cancer at an unknown site, and find a risk of

3.5×10^{-5} yearly at 10 ppm 8-hr. working day

1.4×10^{-4} yearly at 10 ppm continuous exposure

10 ppm in the air adds about

0.7 mg/kg daily to the body weight.

Thus, we can plot the assumed cancer incidence on the graph of figure 3 from Meselson's paper and note that the data confirms that not only is benzene *at worst* a weak mutagen, it is, as expected, *at worst* a weak carcinogen.

THE BASIS FOR INSIGNIFICANCE

30. Table I presents a sampling of the risk associated with a number of man-made and natural occurrences that we face everyday. Although everyone knows that riding in a motor vehicle presents a risk, this risk rarely factors into the decision to make a given trip. At a risk three

orders of magnitude smaller than that of being killed in a motor vehicle accident, no one reasonably worries about being killed in a hurricane; this risk is simply too small to be of concern.

TABLE 1

INDIVIDUAL RISK OF EARLY FATALITY BY VARIOUS CAUSES [6]

(Average Overall U.S. Population in 1969, except as noted)

Accident Type	Total Number For 1969	Approximate Individual Risk Early Fatality Probability/yr
Motor Vehicle	55,791	3×10^{-4}
Falls	17,827	9×10^{-10}
Fires and Hot Substances	7,451	4×10^{-5}
Drowning	6,181	3×10^{-5}
Poison	4,516	2×10^{-5}
Firearms	2,309	1×10^{-5}
Machinery (1968)	2,054	1×10^{-5}
Water Transport	1,743	9×10^{-6}
Air Travel	1,778	9×10^{-6}
Falling Objects	1,271	6×10^{-6}
Electrocution	1,148	6×10^{-6}
Railway	884	4×10^{-6}
Lightning	160	5×10^{-7}
Tornadoes (1953-1971 Average)	118	4×10^{-7}
Hurricanes (1901-1972 Average)	90	4×10^{-7}
All Others	8,695	4×10^{-5}
All Accidents	115,000	6×10^{-4}

31. If we assume a linear relation between cancer incidence and dose it is possible to make a set of simple tables. In Table 2, I have listed a number of hazards, many of which can and possibly should be subject to public attention, for which I have calculated the risk in a very similar manner and with assumptions similar to

[6] Much data assembled by Nuclear Regulatory Commission, NUREG 75/014, and Baldewixz, W., *et al.*, UCLA-ENG-7485, November 1974. See also Statistical Abstract of the United States.

those used to calculate the risk from benzene. These are mostly hypothetical risks. Specific assumptions as to each hazard are discussed in the Appendix. In Table 3 I have listed a number of occupational hazards. Since a risk of 1 in 1 million (or 10^{-6}) is hard to grasp, I have listed in Table 4 several calculated risks of 1 in a million. Some of these are listed in a paper by Sir Edward Pochin.[7]

32. It can readily be seen from Tables 3 and 4 by comparison to hazards which are generally accepted by society that occupational exposure to benzene presents an insignificant risk.

TABLE 2

INDIVIDUAL RISK OF EARLY FATALITY BY VARIOUS CAUSES [8]

(Average Overall U.S. Population in 1969, except as noted)

Accident Type	Approximate Individual Risk Early Fatality Probability/Year
Saccharin, from total consumption	2×10^{-6}
Radiation Cancers: background radiation	1.5×10^{-5}
diagnostic x-rays	1×10^{-5}
1 cross-country airplane flight/year	5×10^{-7}
Cigarette Smoking (Smokers only)	3×10^{-3}
Nonsmoker living with smokers (cancer risk only)	1.5×10^{-6}
Cancer (All types)	1.5×10^{-3}
Air Pollution (U.S. average all sources)	1.5×10^{-4}

[7] E.E. Pochin, The Acceptance of Risk, British Medical Bulletin *31* 184 (1975). (Attachment IV).

[8] See Appendix for discussion of risk estimate for each hazard.

TABLE 3

Annual Risks of Death in Selected Occupations

Coal mining	—	Black lung disease	10^{-2}
Coal mining	—	Accident	1.5×10^{-3}
Airline Pilot	—	Accident	$5 \times 10^{-10-4}$
Typical Jet flying	—	Air accident	10^{-4}
Manufacturing (total)			5×10^{-5}
Benzene worker (10 ppm)	—	cancer	3.5×10^{-5}
Radiation worker at the maximum of 5R/yr		(all cancers)	7.5×10^{-4}
Fire fighters			10^{-3}
Steel worker			6×10^{-4}
Railroad worker		(accident risk)	4×10^{-3}

TABLE 4

Risk of 1 in 1 Million

0.7 cigarette	(cancer, heart disease)
1/2 bottle wine	(cirrhosis of the liver)
10 tablespoonsfull peanut butter	(aflotoxin in mould causes cancer)
1 gallon chlorinated drinking water	(chloroform causing cancer)
30 diet sodas	containing saccharin causing cancer
1 minute	mountain climbing
6 minutes	canoeing
1 air trip Bos.-Was.	(accident risk for either pilot or passenger)
1 air trip (transcontinental)	(cancer risk by cosmic radiation)
1 hr. in a coal mine	(black lung)
3 hr. in a coal mine	(accident)
1-2 weeks	average manufacturing industry
2 weeks	(additional hazard Benzene at 10 ppm)
1 day air pollution in Boston or Washington	

(for some more of these comparisons, and other details, see the paper by Sir Edward Pochin)

The significance of the risk can be seen in still another way. We can ask how much society should pay to reduce the risk. It is in this sense that we should interpret the word "feasible." If we spend all the U.S. gross national product on benzene exposure, we can reduce the concentrations a great deal. But should we do this?

If society spends too much on one risk, the gross national product would soon be exhausted; we can ventilate and put in automatic equipment in coal mines; we can install better equipment, longer runways and better lights at all airports. We can have an army to select unflawed peanuts where the mould containing aflotoxin does not reach the nut. We can install traffic lights, and reduce our efficiency by having a 5 mph automobile speed limit. Any given expenditure may well be considered unfeasible, since too large an expenditure in one occupation can lead indirectly to a *reduction* in safety in other occupations.

If Society wishes to reduce the hazards in various occupations, surely it is preferrable to start on those occupations which are the most risky, and spend money there?

There is some hint in the proposed regulations that the permitted average concentration is being reduced because there is lax enforcement, and that by reducing the standard, the actual concentration can be reduced. But there is practically no correlation; the way of improvement is to enforce the standard; not to change it.

If we apply this concept to the numbers here, each person selling a cigarette should pay a charge of 70 cents *per cigarette* (half of this is a cost to society as a whole and should pay for hospital costs, fire damage, etc.).

In a study performed for OSHA [9] it is estimated that the proposed standard will affect 150,000 people, of which now only 1/5 (or 30,000) have 8 hr. working day average concentrations above the proposed 1 ppm standard.

[9] Compliance tests for benzene emergency standard. U.S. Dept. of Labor, Occupational Safety & Health Administration, May 1977 page 6, 2nd paragraph.

Assuming, for the sake of illustration, that the study is correct, then most of these 30,000 will be exposed at concentrations close to the lower limit so I will assume that 30,000 people are *now* exposed to an average of 3 ppm with an average yearly risk of 10^{-5} at this level. Only a few hundreds would be regularly exposed at 10 ppm. The calculations give 1 leukemia and 1 other cancer throughout all the USA every 6 years. And I reiterate that the number of leukemias and cancers could be zero.

Perhaps industry should try to reduce even this if it is "feasible." It is to be expected that there will be disagreement over what are the costs of this proposed reduction. However, even the lowest figure, calculated in the above OSHA study is $40 million for 6 months corresponding to a cost of $120 million for every hypothetical life saved. Accordingly, I conclude this reduction is not feasible because it will cost too large a fraction of the GNP and leave too little money for other safety measures such as reduction of air pollution, which would yield a much greater dividend in human life.

33. In the proposed emergency standard which precipitated this hearing, the implication is made that the previous Benzene standard took no account of possible carcinogenicity, and that *one* study alone, the Infante study, makes a big change necessary. It is noteworthy that a recent National Academy of Sciences Study on the health effects on benzene [10] reviewed the literature, and found no *proof* of carcinogenesis; only the questionable Infante study has been produced since then. The authors of National Academy of Sciences Studies are rarely reluctant to recommend government action. I find no urge for a reduction of the benzene standard in that document.

34. For all the foregoing reasons, I have concluded that the risk associated with the existing 10 ppm average benzene concentration is so insignificant that it should,

[10] National Academy of Sciences, National Research Council, Health Effects & Benzene, Summer 1976, referred to in Federal Reports, 42, 103 27470 (May 27, 1977).

in my opinion, be acceptable. This conclusion is gained by comparison with the risk associated with other occupational hazards. Even if the Infante study is taken literally, there is no emergency. The risk would still be only equal to the average risk in all manufacturing industries.

APPENDIX A

35. The risk associated with each of the hazards listed in Table 2 has been calculated in a manner similar to that for Benzene exposure. The basis for calculating the risk associated with each hazard is summarized below. For illustrative purposes, the risk estimate for radiation cancer due to one (1) cross-country airplane flight per year is provided in detail.

Cigarette Smoking

36. Here the risk is directly assessed from human data. The risk for nonsmokers living with smokers is roughly estimated from a comparison of the volumes of smoke laden air consumed. Some of my anti-smoking friends think that this may be a "meaningless exercise" since the risk is small and the curve may be non-linear. For comparative purposes, the number certainly has meaning. About 40% of the hazard of cigarette smoking is a cancer hazard; the rest, increased heart disease, etc., it is possible that increased heart disease accompanies other carcinogenic agents in the same proportion, even at lower doses. If so, all other risk calculated from carcinogenic effects must be multiplied by 2.5. The comparisons remain valid.

Saccharin

37. This comes from animal data at high doses and an extrapolation to the *known* total consumption of saccharin in the U.S. The number here comes from the testimony of Dr. Marvin Schneiderman to the Rogers Committee of the U.S. House of Representatives.[11] I have checked his numbers and agree with them.

[11] See also *Federal Register*, April 15, 1977, page 20001.

Radiation

38. Radiation cancers have been studied in humans and animals. I take the numbers here from the Report of the Committee on Biological Effects of Ionization Radiation (BEIR) of the National Academy of Sciences, November 1972. This uses a linear interpolation for low doses also. Radiation works directly on the cell and avoids problems with toxicity at high dose levels.

39. There have been tests with over one million mice at the Oak Ridge National Laboratory. These suggest that the effect at low dose rates is 1/4 of that calculated from this linear curve. This reduces the number from background radiation, but probably not those from diagnostic x-rays or jet airplane flights where the dose is rapid. It is often stated that chemical carcinogens give a smaller insult than radiation, and to this extent a low dose rate effect probably occurs for chemicals. The numbers here remain conservative upper limits.

The Risk of Travelling By Air

40. We are used to the ordinary risk of air travel which is the risk of accident. At the present time, air travel is fairly safe: one death for 300 million miles of travel on a scheduled air carrier.[12] The risk is, of course, concentrated at take off and landing. Nonetheless, I use this to get a figure for the risk of accident for one 3000 mile (cross country) flight; it is 3000/300 million or 10^{-5} One such flight per year gives a risk of 10^{-5} per year.

41. These cross-country airplanes travel at an altitude of 35,000 feet (10 kilometers.) At this height there is an appreciable dose due to cosmic radiation, including neutrons. To estimate this, I use the UNSCEAR report.[13]

[12] Airplane accident deaths often come 100 at a time and the fluctuations are large. Nonetheless, this figure seems to be coming down in the domestic USA; one death in over a billion miles.

[13] Report of the United Nations Scientific Committee on the Effects of Atomic Radiation, UN, NY, 1962, page 201, figure 1. It might be thought that the neutrons would be absorbed by the airplane and the body. Since they are in equilibrium with the surrounding air, this can be allowed for by taking the dose at a lower altitude from the figure. This is a small reduction. (Attachment V).

The dose at a latitude of 55′ N is 2000 millirems/year of ionizing radiation and 3600 millirems/year of neutrons. This will increase markedly during a period of a solar flare.

42. Using 365 days a year, a 5 hour flight at 10 km gives a dose between 3 and 4 millirems. Now, using the relationship between cancer incidence and whole body dose in the BEIR report,[14] I find a cancer risk of 5 x 10^{-7} per transcontinental flight. This is smaller than (1/20 of) the risk of accident and is normally neglected in any discussion of the risks of airplane travel. But it is derived on a comparable basis to the cancer risks discussed here and helps to put them in perspective.

Drinking Water

The numbers here are taken from a recent National Academy of Sciences report.[15] I have made similar calculations, And I am in general agreement. I assume a level of chloroform in the drinking water of 100-200 parts per million (less than reported in New Orleans & Miami). Chloroform has been shown to be carcinogenic in rats and mice.

[14] "The effects on Populations of Exposure to Low Levels of Ionizing Radiation," *Report of the Advisory Committee on the Biological Effects of Ionizing Radiations.* (BEIR) National Academy of Sciences/National Research Council, November 1972.

[15] *Summary Report: Drinking Water and Health,* National Academy of Sciences, National Research Council, Committee on Safe drinking Water, Advisory Center on Toxicology, Assembly of Life Sciences, May 1977. Page 49, table 1. (Attachment VI).

[The following materials are from the administrative record on the percentage-exclusion amendment to the standard. Immediately following are excerpts from the reporter's transcript for May 23, 1978.]

* * * *

[13] QUESTIONS DIRECTED TO MR. WRENN BY MR. LETTOW

MR. LETTOW: Thank you, Judge Ramsey. Mr. Wrenn, during the hearings now under way on the Agency's proposal to establish a generic regulatory structure for carcinogens, you reportedly testified that, and I quote, "Feasibility has consistently been interpreted to mean technical and economic feasibility." End quote. To your knowledge, is this statement an accurate reflection of the Agency's position?

MR. WRENN: I think it is. Not necessarily a full and complete discussion of the issues involved in determining feasibility, but I think that is an accurate expression in the limited form that it is.

MR. LETTOW: Well, the key part of that particular quoted phrase would be an assessment of both technical and economic factors, and the Agency does carry out such an assessment. Is that correct?

MR. WRENN: That has been correct, yes.

MR. LETTOW: Arthur D. Little's study for OSHA, in this benzene—in the original benzene proceeding—focused only on arriage of mixtures containing greater than 1 percent benzene. Has OSHA now updated the A. D. Little study to cover the range from zero to 1 percent?

MR. WRENN: I believe that it is fair to—there has been no additional study of that specific nature; however, [14] the Arthur D. Little study represented only one element of the record on which this issue was ultimately assessed; the preamble of the final benzene standard sets forth the basis for the determinations of the feasibility of the standard as a whole, and the basis for dealing with this issue of percentage exclusion and the feasibility of including or not including such provisions.

MR. LETTOW: Well, maybe I should ask the question in a slightly different way. Does the Agency plan to update the A. D. Little study to cover mixtures with less than 1 percent benzene, specifically?

MR. WRENN: We look to the testimony in this hearing to provide the basis for determining the feasibility and advisability of establishing a percentage exemption for mixtures containing trace amounts of benzene, and what that exemption should be.

MR. LETTOW: In short, you will consider feasibility in making the determination as to a percentage exclusion?

MR. WRENN: Certainly.

MR. LETTOW: What other factors, aside from technical and economic matters, generally will you consider in making this determination?

MR. WRENN: Well, I am not sure that I could usefully give you a catalogue of factors that would enter into every aspect of decisionmaking on health standards, but one need only [15] look at any one of the major health standards to see the range of scientific, technical and policy issues that are considered in establishing the various aspects of the regulation.

MR. LETTOW: This proceeding is following on a number of further proceedings, both before the Agency and courts and you are very familiar with those proceedings. Do you have some specific issues and factors that you plan to address in making the determination as to a percentage exclusion?

MR. WRENN: The proposal which triggered this proceeding attempts to set forth those issues, and I think it adequately does so. I could restate those issues, but I do not think it would be useful to do so.

MR. LETTOW: By those issues you mean the nine questions?

MR. WRENN: Yes. And the context of the proposal itself, the discussion of those issues.

MR. LETTOW: Does OSHA plan to consider dermal exposures in establishing a percentage exclusion?

MR. WRENN: The proposal does not distinguish between various routes of exposure to benzene. It simply raises the question of whether it is necessary and appropriate to establish an exemption to amend the final standard for benzene by establishing an exemption from coverage of any of the provisions of the standard—mixtures containing so-called trace amounts of benzene. And the exemption as proposed in the [16] Federal Register notice would be an exemption from all provisions of the regulation.

MR. LETTOW: Question six says, "What airborne concentrations of benzene result from the percentage of benzene in each product?" Is that going to be a special factor in making the determination as to a percentage exclusion?

MR. WRENN: That is certainly a matter of interest to the Agency in setting any exemption for benzene-containing substances. Since the standard itself establishes a permissible exposure limit for benzene, we would certainly endeavor to set an exemption which assured that employees exposed to materials exempt from coverage under the regulation are subject to no greater exposure than employees who are subject to the provisions and protection of the standard.

MR. LETTOW: Why is there—

MR. WRENN: One of the questions that was raised in the earlier rulemaking and one of the questions that is raised here is the question of the likelihood that exempting any particular category of materials from regulation, under the benzene standard—the likelihood that that exemption would provide a basis for being confident that workers involved with those exempt materials would not be exposed in a manner that was intended to be avoided by the benzene regulation.

MR. LETTOW: Why is there not then also a comparable question or a point specifically addressed toward dermal [17] exposure?

MR. WRENN: I suppose primarily—as a practical matter, primarily because there is no quantitative measure in the benzene standard or any other regulation dealing with toxic substances such as benzene—no quantitative measure is typically associated with dermal contact with materials like benzene. And yet, inhalation exposure is readily quantified and a fundamental aspect of the regulation is usually the establishment of some limit to the exposure to airborne vapors and gases.

MR. LETTOW: Does OSHA have any factual information on levels of dermal absorption of benzene, beyond the very small amount of information in the original hearings in standard-setting proceedings?

MR. WRENN: I am not fully aware of the materials we have received to date in this proceeding. The preamble to the final standard for benzene discussed the evidence in the record which was related to the dermal hazard from benzene.

MR. LETTOW: I will try that one again a different way. Does OSHA have any current plans to obtain dermal absorption data?

MR. WRENN: No. Other than through the normal process of acquisition of information of this sort for benzene and a host of other toxic substances.

MR. LETTOW: Does OSHA have any current work of any [18] kind under way to determine whether or not a hazard exists from dermal exposure to mixtures containing small amounts of benzene? That is, within the range that we are talking about with this percentage exclusion.

MR. WRENN: What do you mean by work under way?

MR. LETTOW: Do you have any studies now being performed by contractors, or do you have any plans, for example to have contractors perform any such studies?

MR. WRENN: That is not generally the nature of OSHA's activities. We look to other parts of the scientific community, including NIOSH, NCI and the academic and private and research activities to provide the information on which we assess the hazards of worker exposure to toxic substances and establish regulatory requirements.

MR. LETTOW: Does NIOSH have any such work under way, or have you worked with NIOSH to establish a program for collecting such information?

MR. WRENN: I am unaware of work of this nature under way by NIOSH.

MR. LETTOW: Has OSHA studied the desirability or necessity of establishing a dermal contact limit, similar to the permissible exposure level for air contaminants set in the standard?

MR. WRENN: OSHA has recognized the importance of—and particularly, the current Assistant Secretary, Dr. Bingham—[19] has recognized the importance of skin contact with toxic substances in the workplace as being a major factor in occupational disease, ranging all the way from acute dermatitis to chronic disease, or the contribution to the risk of chronic disease from skin absorption of toxic substances. And because of that, we have established an Ad Hoc Standards Advisory Committee which is meeting during this time to evaluate the importance of percutaneous absorption and other means of skin contact with toxic substances in the workplace, and to recommend to the Agency appropriate regulatory actions to deal with these problems.

JUDGE RAMSEY: Mr. Lettow, you have about 5 minutes.

MR. LETTOW: That is fine, I just have several more questions and then I am ready to sit down. I think it is my cold, but in any event, what is OSHA's present timetable for acting in these rulemaking proceedings?

MR. WRENN: For acting in which rule—

MR. LETTOW: In these.

MR. WRENN: In this present.

MR. LETTOW: That is correct.

MR. WRENN: The instant proceeding, as you would say. Our intention, as we have indicated in our opening remarks and in the proposal, and before the courts is to act as expeditiously as possible. I do not have a publication date that I can give you for a final decision by the Agency, but we do intend to [20] issue a final decision on the basis of the record developed in these proceedings as rapidly as possible.

MR. LETTOW: I am going to ask you to make some assumptions that I will give you as a hypothetical case. Assuming that a study were now under way of absorption

of benzene through skin, and that the results of such a study could be made available to OSHA within 180 days, would you change your projected timetable in acting in these particular proceedings?

MR. WRENN: No, sir.

MR. LETTOW: All right. Your Honor, I think that is going to do it. With that, we will turn it over to you or someone else.

MR. WRENN: Let me add to the answer to the last question. I am rarely allowed to get away with a yes or a no in these proceedings.

(Laughter.)

MR. WRENN: I would add that one of the basic charges that OSHA has, from the Congress and through the Occupational Safety and Health Act, is to set standards for protection of workers based on the best available evidence. And in this case, we have already concluded a rulemaking, a lengthy rulemaking, a rulemaking which involved extensive public participation, and we believe the record in that proceeding represents the best available evidence for setting a standard [21] for benzene. On the one narrow question of the scope of this regulation which covers benzene which has been described as a ubiquitous material and arising in many forms in the workplace and in the consumer environment, we have determined that it was appropriate to reexamine the issue of scope and the issue of percentage exclusion because there appeared to be evidence that was not brought to the record of the original proceeding that would be immediately available for consideration by the Agency. In that sense, it would be inconsistent with the purposes we have set for this rulemaking to defer further decision on this matter for a period as long as 180 days or any other significant period.

Now, if information comes available on benzene or any other regulated substance, or unregulated substance, which significantly changes the perception in the scientific community and the regulatory community of the hazard of exposure to a substance or the appropriateness of existing regulation, it is our business to examine

that evidence and to reexamine any actions we have taken or not taken in the face of that new evidence, and we would do so. But I think the earlier answer of "no" is an appropriate response to the question of whether we would defer decision in this proceeding for as long as 180 days, awaiting the results of a study, the nature of which results could not possibly be known at this time.

[22] MR. LETTOW: Your Honor, I think I liked the "no" answer better, but then in any event, I just have one further question after that statement. Would you agree, Mr. Wrenn, that in effect the percentage exclusion level would act as the permissible exposure limit for dermal contact in the standard, as the standard is now written?

MR. WRENN: I do not think it serves in any analogous way as a quantitative and readily measurable airborne exposure limit.

MR. LETTOW: Well, I did not say airborne exposure limit; I was actually referring to the fact that if you had a permissible or a percentage exclusion, would that percentage exclusion act to exempt someone from the dermal contact provisions of the standard?

MR. WRENN: The percentage exclusion, as we contemplated it and as the proposal discusses it and as the earlier rulemaking discussed it, is simply—it simply acts to alter the scope of the regulation; that is, determine whether it applies or does not apply. It, I think, serves no purpose other than that. That is an important purpose. Surely the scope of a regulation is a very important aspect of a regulation. But I think that it would be meaningless to characterize the scope of the application as serving, in the way we normally think of a permissible exposure limit, as a permissible exposure limit.

[23] MR. LETTOW: Mr. Wrenn, would you agree that the scope of the various sections of the standard that bear on the airborne contaminant levels is affected by the action level concept?

MR. WRENN: Most of the requirements of the regulation are deemed to apply or not in relation to the degree of employee exposure. For those employments

covered by the scope of regulation, in both the action level and the permissible exposure limit, play a role in determining which of the obligations of the standard apply in any given set of exposures.

MR. LETTOW: Thank you, Your Honor.

* * * *

[126] STATEMENT OF ROGER W. STRASSBURG, DIRECTOR OF ENVIRONMENTAL AFFAIRS, B.F. GOODRICH COMPANY

DR. STRASSBURG: Your Honor, Judge Ramsey, ladies and gentlemen, I am Roger S. Strassburg, Director of Environmental Affairs for the B.F. Goodrich Company. With me today on the panel are Ernest Bean, Assistant General Counsel of the B.F. Goodrich company, and on his right, E.T. McDonel, Manager of Tire Materials Research [127] of B.F. Goodrich Tire Division, and on my left, Carl Draves, Jr., Director of Materials and Compound Development, of the B.F. Goodrich Tire Division. What we have done is to prepare a written statement that examines in detail nine questions that the Agency asked concerning possible revisions in the benzene standard. This statement and supporting documents have been submitted prior to this hearing in order that they may become part of the record of the proceedings, and they are noted as S2, I believe, and I would like to move that they become a part of this record.

* * * *

DR. STRASSBURG: I hope that the information that we have submitted will help you in the development of a suitable percentage exclusion, whereby certain work operations will not be included in the scope of the final benzene standard and I hope that our statement gives you some perspective for [128] the concerns that Goodrich has regarding the final benzene standard as it was promulgated in February.

Rather than reading directly from our written, I would like to review briefly the main points that we believe should be considered when reformulating the permanent standard for controlling the use of benzene in the work-

place. After my presentation my colleagues and I will be happy to try to answer any questions that you may have.

As you know, Goodrich participated in the original benzene rulemaking. At that time, we urged that the standard not apply to work operations where liquid mixtures containing one percent or less of benzene are used. However, any concept of a proposed percentage exclusion was deleted when the final standard was issued, and Goodrich is now unable to comply with that standard. In fact, the present standard provides unsolvable problems for us because of the very nature of our operation. Two of our domestic divisions manufacture tires and other rubber products. These operations used petroleum solvents that contain trace amounts of benzene. Another division of our company manufactures cements, adhesives and sealants and therefore uses various grades of petroleum solvent containing residual benzene.

Another division produces and uses various raw materials commonly referred to as petrochemicals, which are derived from petroleum and thus have trace amounts of benzene.

[129] Therefore, Goodrich has a vital stake in any standard that applies to benzene, and to help construct a more realistic standard we have three recommendations. First, provide for an exclusion level of a tenth percent benzene or less in liquid mixtures below which the standard does not apply. Second, establish a special action level of a half a percent benzene in liquid mixtures for the dermal contact sections of the standard only. And third, re-write the labeling provisions of the standard so that the "cancer hazard" label does not apply to liquid mixtures or products containing unavoidable benzene contamination.

I would like to discuss each of these in turn. Goodrich's particular concern, aside from labeling and dermal contact, with a regulatory strategy without a percentage exclusion is that such a strategy is imprecise and lacking in objective criteria whereby appropriate health precautions are initiated. Benzene is renown for its ubiquity. Yet, the mere presence of benzene, however minute, in

liquid mixtures automatically triggers significant regulatory requirements, such as initial monitoring, training, recordkeeping, the dermal contact prohibition and labeling. A standard based on this premise is simply not realistic. Let me illustrate why this is the case.

Using special analytical instrumentation called a gas chromatograph mass spectrometer we have detected [130] benzene concentrations in the range of one to six parts per billion in process water used at one of our manufacturing facilities. Furthermore, we believe that benzene has been present in significant parts per billion in all petroleum-based organic materials that have been analyzed to date. And benzene may be present in minute quantities in other raw materials and products. In addition, the National Academy of Sciences recently announced that benzene had been detected in drinking water.

Therefore, with a final benzene regulation to remain in effect without a specified percentage exclusion, we believe the standard would be quite arbitrary and unreasonable. In fact, the fact that a scientifically sophisticated employer had the analytical capability to detect benzene in liquid solutions where benzene is clearly a trace contaminant could trigger regulatory compliance. In fact, by providing a drinking fountain an employer could be subject to the initial monitoring, training, recordkeeping, dermal contact prohibition, labeling provisions of the standard. Clearly, without a percentage exclusion we could venture into the realm of unreality.

A specified percentage exclusion is needed to eliminate such concerns. A specified percentage exclusion might also eliminate, to a substantial extent, the controversies over whether compliance by Goodrich or other companies [131] is feasible.

As a consumer of various types of petroleum-based solvents, we find ourselves at the mercy of suppliers concerning the benzene content in their products. Goodrich's specification for the level of residual benzene in rubber-freshening solvent has fluctuated from two and a half percent to two-tenths percent, depending upon the commercial availability of low benzene solvents. Since late

1977, our benzene specification has remained at a half a percent and all of our rubber-freshening solvent suppliers have met that specification.

Lower specifications, however, jeopardize supply and would require the entire rubber industry to rely on the one supplier that at this time has been able to reduce benzene content to meet the requirements of the proposed tenth percent benzene standard. To expect a single supplier to meet the entire industry's need for solvent is completely unrealistic, particularly when only one-half of the entire industry needs can be met in the foreseeable future. Likewise, it is not feasible, either technically or economically, for us to remove benzene from the solvent after they have supplied it to us. Therefore, Goodrich and the entire rubber industry is dependent upon our suppliers in the petroleum industry to reduce the residual benzene levels in their products to the lowest feasible levels obtainable [132] by their technology.

Since it is virtually impossible for us to receive solvent without some trace of benzene, we support strongly the concept of a specified percentage exclusion at some level for the reasons previously stated. However, Goodrich cannot support and strongly objects to the proposed one-tenth percent benzene exclusion level for liquid mixtures, as applied to the dermal contact prohibition section of the standard. As a member of the rubber industry, Goodrich requests relief from the dermal contact prohibition section above and beyond the proposed tenth percent benzene percentage exclusion. Our proposal is that OSHA adopt a special action level of half a percent benzene in liquid mixtures for the dermal contact section of the standard. We call our proposal a special action level in order to emphasize that it would apply only to the dermal contact sections of the standard. It would be distinct from the general tenth percent benzene exclusion proposal. We believe it is essential that a half a percent level for dermal contact be established for several reasons.

First, the tire industry cannot operate without some dermal contact with rubber-freshening solvent that is contaminated with trace amounts of benzene. The actual building of tires and the critical placement of layers of

rubber-stop require that at least a portion of the fingers [133] or palm of at least one of the builder's hands comes into contact with the swab used to apply the freshening solvent. We have studied the possibility of completely avoiding dermal contact with solvent by the use of gloves or barrier cream. Our research indicates that protective gloves are not practical; in fact, they are unsafe. Barrier creams do represent a possible way to protect workers from the absorption of benzene into the skin. However, the use of barrier creams poses such problems as the effect they would have on the adhesion properties of cured tires. Moreover, the use of barrier creams would require constant monitoring to ensure that the correct amount of the cream was applied at the proper intervals, possibly up to six times during an eight-hour shift. Therefore, at this time we believe that further studies are necessary before the unqualified use of barrier creams can be endorsed.

There is a second reason why a special action level should be adopted for skin contact. The standard as it is now written, calls for a prohibition against dermal contact but is not supported by scientific evidence. Skin absorption is recognized as a secondary health hazard and should be regulated as such. The present standard ignores this fact. The primary hazard presented by benzene exposure—that is inhalation—is permissible at levels up to one PPM/TWA. Yet in the case of potential skin absorption, which is a [134] secondary hazard at best, the standard prohibits skin contact with liquid altogether. We challenge the reasonableness of a standard that permits some exposure to a carcinogen via the primary route of entry and prohibits any exposure from the secondary route of entry.

Our third reason for supporting a change in the dermal contact standard is that a special action level does not prevent other protective measures from coming into operation. For example, if Goodrich or others in the rubber industry are unable to obtain a tenth of a percent benzene rubber-freshening solvent, and are forced to use a half a percent benzene concentration solvents in order to build tires, a special action level in no way exempts us

from the initial monitoring, training and recordkeeping provision of the standard. Thus, workers would be protected while what OSHA admits is a very real problem for industry would be solved. We believe that relief from the present provisions of the standard regarding dermal contact are absolutely essential and we would urge that a special action level of a half a percent benzene be adopted.

Also of concern is the provision of the standard that deals with labeling. As I mentioned earlier, Goodrich supports the proposed percentage exclusion of a tenth percent because of its elimination of regulatory activity triggered by the presence in the workplace of ubiquitous benzene as a [135] trace contaminant in liquid mixtures. If triggering of the labeling provision is not eliminated, along with the elimination of such requirements as initial monitoring and employee information and training, Goodrich would be faced with the unsolvable problem of not knowing what it was required to label because of lack of an objective standard for determining the presence or total absence of benzene. Moreover, there should be no requirement for the cancer hazard label on mixtures containing benzene in concentrations between the percentage exclusion and those permitted by a special dermal contact action level. There is no evidence of a cancer hazard from touching such liquids, and labeling them would be confusing to our employees. All possible health effects including dermatitis could best be explained as a part of the employee information training program.

Therefore, Goodrich believes that the labelling provision of the standard as promulgated is unnecessary, and we strongly urge that OSHA, in this present rulemaking, rewrite the section of the standard involving labeling.

From my remarks and from the comments of others testifying today, I am sure you can appreciate the importance we attach to the final benzene standard. My comments today reflect our concern that the final standard achieves workplace health without presenting insurmountable problems to our industry. I am hopeful that a standard accommodating these [136] dual objectives will emerge from this hearing. Thank you, and we would be happy to try to answer your questions.

* * * *

QUESTIONS DIRECTED TO DR. STRASSBURG BY SOLICITOR'S OFFICE

MR. ESTEP: Now, let me see if I have got this straight. You are the ones with the blimp, is that right?

DR. STRASSBURG: We are the other guys.

MR. ESTEP: First let me see if I understand your position as far as this proposed dermal action level. You are suggesting that a tenth of a percent exclusion hold across the board. However, for purposes of whatever that very special section on scope and application concerning the dermal exposure, that there be an exclusion of five-tenths of a percent only for dermal?

DR. STRASSBURG: Right.

MR. ESTEP: So this would mean that a tire builder, while he can touch five-tenths of a percent, would still have—the employer would still have to meet the permissible [137] exposure limit of one part per million in the ambient air. Is that correct?

DR. STRASSBURG: That is right.

MR. ESTEP: So that the employer who is working—an employee who is working with a solvent of three-tenths of a percent, he can touch it but the ambient air still has to be below one part per million.

DR. STRASSBURG: Right.

MR. ESTEP: And let me again make it clear that that is your proposal; it is not—that was not articulated in the proposal for this rulemaking, but it is an alternative.

DR. STRASSBURG: Right.

* * * *

[139] MR. ESTEP: On page 13 of your statement at the bottom, without getting into the question of health effects, you have mentioned, "Further calculation indicates a maximum actual skin absorption of a tire builder's use of one percent benzene rubber-freshening solvent would result in approximately one-third the exposure permitted by the permissible exposure limit." I wonder if you can explain what you mean by that. I know that you

have in your research section, which is D, some data there, but it is a fascinating statement and if it were true, it could have some effect on this dermal action level that you are suggesting. I think it is on page three of D. Do you want to direct me?

DR. STRASSBURG: Okay, I have page three now.

MR. ESTEP: I am asking you to explain that correlation. I think on page three of D, under (a), is some sort of an explanation, but I would like you to [140] clarify that or explain it.

[141] DR. STRASSBURG: I am going to ask Mr. McDonel if it is all right to do that.

MR. ESTEP: Certainly.

MR. MCDONEL: What we tried to do was sort of an experimental calculation to determine what sort of dermal exposure a worker would do in a worst case situation, and here we attempted to be very conservative, much like accountants do, and we obtained the data that if a worker were exposed to one part per million benzene—this was the action level, or the maximum permissible level in eight hours, that according to the industrial hygiene and toxicology reference we gave there, he would be exposed to about 28.8 milligrams of benzene in eight hours.

Are you with me so far?

MR. ESTEP: I think so. You are saying that if he is going to breathe so much of a volume of air, the total exposure over a time weighted average, an eight-hour time weighted average, would be approximately 28.8?

MR. MCDONEL: Yes, we used this as a base reference. We wanted to know on how much maximum exposure a tire builder could come in contact with over an eight hour period.

MR. ESTEP: Does this approach have any scientific precedent in calculating total exposure to a substance? Or is this sort of a new approach taken by you?

MR. MCDONEL: Well, maybe this is our original [142] approach. We felt that we needed to have some basis in order to put some perspective on how much benzene exposure would a tire maker be exposed to, and

we wanted to know what the exposure level was just from the one part per million level. We did a calculation in Part A, and that is the calculation we came to there.

MR. ESTEP: Okay.

MR. MCDONEL: And then we took a very conservative estimate. We know the number of exposures that a tire builder will have on an eight-hour shift in building a tire in a worst possible case situation.

MR. ESTEP: And that is 30 contacts?

MR. MCDONEL: Yes.

MR. ESTEP: And that is where he takes the fabric swabs—

MR. MCDONEL: Yes.

MR. ESTEP: —and he rubs it on a tire—

MR. MCDONEL: Yes.

MR. ESTEP: —and he puts the swab back?

MR. MCDONEL: Yes. Only we did it in a much more conservative way. We determined how much solvents your hand would pick up if you dipped your hand in up to the wrist, to determine the loss or the amount of solvent your whole hand would pick up. Now, this is a factor of ten to 100 excessive, really, because you do not really pick up that [143] much, but we wanted to have some sort of basis for judgment and if, you know, rather than guessing, we just decided to try it and find out.

MR. ESTEP: How did you calculate the amount to remain on the hand?

MR. MCDONEL: We put the solvent in a glass beaker and weighed it on a scale, and then we dipped our hand into it, removed the hand, and noticed the loss in weight.

MR. ESTEP: You dipped the hand in and out?

MR. MCDONEL: Yes. It is a very simple experiment.

(Laughter.)

JUDGE RAMSEY: Your question, Mr. Estep.

MR. ESTEP: Could you proceed with the—

MR. MCDONEL: The explanation?

MR. ESTEP: Yes, the explanation.

MR. MCDONEL: Well, then it is very simple mathematics to calculate the amount of the benzene exposure, if you would assume that all of the benzene that was in the rubber solvent at that time went through the skin, which again—

MR. ESTEP: But that is an assumption you are making that that amount is absorbed.

MR. MCDONEL: That is the assumption we made, and that is not a true assumption, necessarily.

MR. ESTEP: Okay.

[144] MR. MCDONEL: This was just for a matter of calculation, a matter of comparison.

MR. ESTEP: This accounts for your later statement that it is a worst case analysis, far in excess of actual exposure?

MR. MCDONEL: Yes.

MR. ESTEP: Okay.

MR. MCDONEL: This merely puts the thinking in perspective as to where we stood when we were—just what were we exposing the tire builders to? And I think that this is a very important calculation, because it had not been done, and nobody really came up with objective comments as to what was the extent of the exposure on the dermal contact. I believe that calculation puts some perspective on that.

MR. ESTEP: Then your conclusion is, then, it is roughly equivalent or it is less?

MR. MCDONEL: Yes, than the permissible one part per million time weighted average.

MR. ESTEP: And that is the worst case analysis, which could be 100 times greater than the actual exposure? This is not based on any scientific data which suggests rate of absorption?

MR. MCDONEL: No, it is not. It is only based on the amount of solvent contact that would be done. Now, we [145] have rerun those experiments in which we have been more realistic, and found that instead of the 2.94 grams pick up which we have there, we have come out more with a three-tenths per gram pick up if you just

dip your fingertips in to the first knuckle, or the second knuckle.

MR. ESTEP: Okay, thank you.

* * * *

[209] STATEMENT OF ROY N. JOHNSON,
THE GENERAL TIRE AND RUBBER COMPANY

* * * *

[210] MR. JOHNSON: Yes. My name is Roy Johnson and I am Corporate Director of Safety and Health for The General Tire and Rubber Company. I will be presenting General's comments on the proposed amendments to the benzene standard.

Each of General's three major divisions, the tire division, chemical division, and industrial products division, is affected by the permanent benzene standard. Each of these divisions involves high volume production operations which use solvents containing small amounts of benzene.

I want to emphasize that these operations cover a broad range of products ranging from tires to tennis balls to materials for luggage, footwear, shower curtains, credit cards and to plastic parts for the auto industry. Clearly, General's 15,000 products cover all sections of the nation's economy.

[211] General long ago recognized the hazardous nature of pure liquid benzene. With the exception of perhaps some necessary laboratory applications, no liquid benzene is used by the company. However, as noted, large quantities of commercial solvents and adhesives are utilized and essential to the continued operation of General's manufacturing facilities which affect a broad spectrum of the nation's business and industry.

Due to the Company's large volume requirements, laboratory grades are unavailable in sufficient quantity. Rubber makers' solvents, as well as various other solvents and adhesives used by the Company do contain some percentage of benzene as a naturally occurring contaminant, and General knows of no source of commercial grade solvents or suitable solvent substitutes which are totally benzene free.

I would now like to address the issues outlined in OSHA's announcement of this proceeding very briefly. With respect to the question of whether there should be a percentage exclusion, General believes that certain work operations should be exempt from the standard where the sole exposure to benzene is from liquid mixtures containing less than a specified percentage of benzene. General believes that the present strict prohibition against skin or eye contact with liquids containing any amount of benzene is unreasonably restrictive.

First, the restriction is unreasonable in light of the unavailability of commercial grade rubber makers' solvents, [212] or printing ink solvents that are totally benzene free.

Second, although General's operations are highly automated, certain operations, such as the assembly of tires, as you have previously seen, or the assembly of tennis ball components, require the accuracy of hand assembly, making total avoidance of skin contact with solvents an impossibility.

General therefore believes that an exemption from the skin and eye contact prohibition is absolutely required so that critical manufacturing processes in production of numerous consumer and industrial products can continue. In the absence of such exemption, General and the rest of the industry would be required to elect between stopping production or continuing operation in violation of OSHA's permanent standard.

General also believes that if the percentage of benzene adopted as the exemption level is sufficiently low, exemption from the provisions of the entire standard would be appropriate. However, in the absence of a total exemption, there must be relief from the impossible situation created by the provisions prohibiting dermal and eye contact.

General does not believe that the 0.1 percent benzene is the appropriate percentage for an exemption. We, as well as other members of the rubber industry, require large volumes of commercial grade solvents. Based upon availability in the marketplace, my company believes that a minimum of 0.5 percent, and ideally, 0.7 percent, would

be an appropriate percentage [213] upon which to base an exemption for the dermal and eye contact. Solvents at or below 0.5 percent appear to be available in sufficient quantities to allow most industrial locations to continue operations. And while it is true that some suppliers are able, at least on occasion, to supply solvents to some geographic locations as low as 0.1 percent benzene content, these same suppliers are not able to supply the needs of the entire industry or to guarantee a consistent quality at such low levels.

The Company would also support a planned reduction in the adopted percentage but believes that such reduction should only be adopted when the solvent producers have the capability to deliver commercial grade solvents in sufficient quantity and at consistent levels of benzene content.

Rubber makers' solvents utilized in the manufacture of such items as tires, tennis balls and rubber industrial and commercial products vary considerably with respect to the benzene content. General has been monitoring shipments at various facilities throughout the country, and in recent experience found only one shipment exceeding one percent. Most suppliers fall within a range of 0.2 percent to 0.75 percent.

Benzene levels in some limited number of shipments have measured 0.1 percent or less, but only one or two small suppliers known to General seem to be able to deliver 0.1 percent or lower solvent on a consistent basis. [214] It should be noted that these suppliers are unable to supply General's needs let alone those for the entire industry. I am told by our technical staff that other petroleum derivative solvents are not acceptable substitutes, and in most of these a trace amount of benzene is found to exist also.

On a related issue, you have asked how far can the benzene content of products be feasibly reduced. General does not have sufficient knowledge to respond to this question.

General studies conducted to date indicate as a rule the lower the benzene content of the solvent, the lower the individual exposure to airborne exposures. From a

0.1 percent benzene solution and 0.5 percent benzene solution, such factors as work practices, nature of the operation, and air handling equipment appear to have a more significant impact on airborne concentrations than does the benzene at levels at or below 0.5 percent.

Where the percent of benzene in solvent is at or below 0.5 percent and the work operations are properly controlled, most employee exposures to airborne concentrations remain below the permissible level. There are, however, some exceptions and even a 0.1 percent solution could produce exposures above the actual level.

General believes that if a dermal exemption is granted at 0.5 percent, airborne concentrations can be held below the action level with improved work practices and air [215] handling equipment.

With respect to labeling, General believes that liquids exempted from the benzene standard due to their extreme low percentage or benzene content should also be exempted from the labeling requirements of the standard. First, uncontrolled use of the warning label certainly dilutes the effectiveness of the warning message.

Secondly, if the lower percentage of benzene in the liquid reduces the hazardous nature of the solution sufficiently to entitle it to exemption from the other provisions of the standard, there appears to be no logical reason to require manufacturers to undertake the time consuming and expensive process of applying labels to otherwise safe containers of liquids.

As the last member of the rubber industry witnesses, I would like to take a moment to summarize my view of the industry's position. Each of the rubber companies, as well as the RMA, has indicated support for a percentage exclusion. The data which has been submitted indicates the percentage exclusion should be at least 0.1 percent.

But the rubber industry has a special problem which requires more than a percentage exclusion. Given the need for dermal contact in tire building and other operations, the rubber industry requires a special exemption level for dermal contact with liquids with small amounts of benzene. That [216] special dermal exemption level

should be set at 0.7 percent benzene or a minimum of 0.5 percent benzene.

Because of the industry's dependence on outside suppliers, perhaps the best approach would be a 0.7 percent level initially, to be reduced in stages to a 0.5 percent as suppliers can meet the lower levels. The results of Dr. Maibach's study which was discussed earlier certainly should bear directly on the exemption level finally chosen.

Thank you very much for the opportunity to testify.

* * * *

[Amend Exh. 32-F-2]

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 78-1486

THE RUBBER MANUFACTURERS ASSOCIATION, INC., *et al.*, PETITIONERS,

v.

EULA BINGHAM, As Assistant Secretary of Labor for Occupational Safety and Health, *et al.*, RESPONDENTS.

On Petition for Review of Action by the Assistant Secretary of Labor for Occupational Safety and Health

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MOTION FOR STAY

TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT, THE HONORABLE JUDGES THEREOF:

Petitioners in the above-styled cause respectfully move this Court to stay the effectiveness of Sections (c)(2), (h), and (k)(2)-(5) of the permanent benzene standard (29 C.F.R. §§ 1910.1028(c)(2), (h) and (k)(2)-(5)) as promulgated by Order of the respondent, Eula Bingham. These portions of the permanent benzene standard are the subject of the Petition for Review in this proceeding.* This motion is made on the grounds that petitioners are likely to prevail on the merits of this Petition

* The Petition for Review was initially filed in the U.S. Court of Appeals for the Sixth Circuit, and docketed there as No. 78-3114. By order of the Sixth Circuit entered on March 9, 1978, the Petition for Review was transferred to this Court, because of the pendency of the prior-filed petitions for review in *American Petroleum Institute, et al.* v. *Occupational Safety and Health Administration*, Nos. 78-1253 and 78-1257 (5th Cir.).

for Review, they will be irreparably harmed unless a stay is granted, no substantial harm will be incurred by other interested persons through grant of a stay, and there will be a benefit to the public interest and no harm to the public interest through grant of a stay. The grounds upon which this motion are based are more fully set forth in the accompanying Memorandum of Points and Authorities in Support of the Motion for Stay and the affidavits attached thereto.

On March 3, 1978, application for a stay was made to respondents. At 3:35 p.m. on March 9, 1978, counsel for Petitioners received a "statement" of respondents' intention to grant partial relief. A copy of this "statement" is attached. To counsel's knowledge, as of the time of filing this motion the respondents have not actually granted any relief.

Oral hearing is requested if the Court should deem it appropriate.

Respectfully submitted,

/s/ Charles F. Lettow
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Counsel for Petitioners

OF COUNSEL:

CLEARY, GOTTLIEB, STEEN & HAMILTON

March 10, 1978

U.S. DEPARTMENT OF LABOR
Occupational Safety and Health Administration
WASHINGTON, D.C. 20210

Office of the Assistant Secretary

The following statement was made orally on March 8, 1978 to parties seeking a response by that date to their requests for an administrative stay by OSHA of certain provisions of the permanent benzene standard, 43 Fed. Reg. 5918-5970, Feb. 10, 1978. Individual written responses to the various parties will also be made. The text of the oral statement is as follows:

Except as stated below, we are denying the parties' requests for relief:

1. The agency is correcting the preamble to the benzene standard in a correction document which will be available at the Federal Register Office as soon as possible. That document will state that OSHA interprets the reference to solids in the definition of benzene to apply only to pure solid benzene and *not* to solids which contain benzene.

2. OSHA is going to stay the standard as it applies to work operations where the sole exposure to benezene is from mixtures containing 0.1% or less of benzene. This decision will be announced in a Notice of Proposed Rulemaking and Notice of Stay in the Federal Register and OSHA will be soliciting additional information on the percentage exclusion issue. This decision will be announced in an official news release either this week or early next week.

[Amend. Exh. 32-F-2]

* * * *

AFFIDAVIT OF JAMES R. SANKEY
OF THE GOODYEAR TIRE & RUBBER COMPANY
IN SUPPORT OF MOTION FOR STAY

STATE OF OHIO)
) ss.
COUNTY OF SUMMIT)

JAMES R. SANKEY, being duly sworn, deposes and says:

1. I am now and have been for the past three years Director of Domestic Tire Production for The Goodyear Tire & Rubber Company ("Goodyear"), an Ohio corporation with its principal offices located in Akron, Ohio. I have been employed by Goodyear for thirty five (35) years in various capacities relating to the manufacture of tires for automobiles, trucks and other wheeled vehicles and have managed tire plants in Akron, Ohio; Union City, Tennessee; and New Delhi, India. I am personally familiar with all aspects of the process of manufacturing automobile, truck and related type tires.

2. Goodyear is the world's largest manufacturer of tires and produces more tires in the United States than any other tire producer.

3. As Director of Domestic Tire Production, I am directly responsible for the operations of eight (8) domestic tire manufacturing plants owned and operated by Goodyear. These facilities are located in Akron, Ohio; Danville, Virginia; Gadsden, Alabama; Jackson, Michigan; Los Angeles, California; Madisonville, Kentucky; Topeka, Kansas; and Union City, Tennessee. Collectively, these facilities employ more than 15,695 persons in manufacturing and related operations. I am personally familiar with all aspects of the operations at each of these facilities.

4. I have read and am familiar with the permanent standard of the Occupational Safety and Health Admin-

istration for the regulation of occupational exposure to benzene (29 CFR 1910.1028, 43 *Fed Reg* 5917, Feb 10, 1978) (the "Benzene Standard"). I have particularly reviewed the sections of the Benzene Standard dealing with dermal and eye contact with liquid benzene, 29 CFR 1910.1028(c)(2) and (h) (collectively referred to as the "Dermal Contact Sections").

5. As written, Goodyear is unable to manufacture tires in compliance with the Dermal Contact Sections of the Benzene Standard, as described below. Goodyear will suffer irreparable harm if the Dermal Contact Sections of the Standard are not stayed.

6. The use of petroleum solvents is essential to the manufacture of tires. These petroleum (or "rubber") solvents are used as tackifying agents in the tire building process. The manufacture of tires involves, among other things, attaching layers of material ("plies") together to construct tires. Solvent is applied with a swab to each tire ply and other components' surfaces to insure sufficient adhesion for the components to hold a fixed position during the building operation. Precision tolerances are critical for tire uniformity and compliance with safety standards. Tires are built on a moving drum, and excess liquid solvent can be splattered or thrown off in the process. All placement and fitting of component parts is done manually by the builder, and the operator's hands are in constant contact with surfaces that have been activated by petroleum solvents containing benzene. This manual contact with surfaces is essential to the builder, not only in applying layers of material to the tire, but also detecting wrinkles and other defects in the ply application from the "feel" of the tire. The degree and frequency of dermal contact with these solvents varies with the size and type of tires being built, and the speed at which the building drum rotates. The larger the tire being built, and the larger and heavier the component plies, the more solvent will be used and the more the operator's hands must be in contact with the tire surface. There is no suitable substitute for the use of petroleum solvents in this process.

7. Petroleum solvents suitable for the tire building operation contain trace amounts of benzene as an impurity. Goodyear has requested all major suppliers of petroleum solvents to provide Goodyear with solvents that do not contain any amount of benzene. These suppliers advise Goodyear that it is not feasible to remove all the benzene from petroleum solvents used in the construction of tires.

8. To comply with the Dermal Contact Sections of the Benzene Standard, it would be necessary for employees engaged in attaching plies to wear face and eye protection, protective clothing, and gloves or other protective covering for the hands. In the builidng of certain types of passenger car and radial tires, the introduction of more automated building machinery may permit the operator to wear protective gloves, as the need for sensitive manual contact with the tire during building is reduced. On other tire types, such as farm and tractor, and off-the-road tires (earthmover tires, etc.), even if it were possible for employees to effectively perform their functions while wearing gloves, it is not possible to equip them with skin-tight, impervious gloves which would not dissolve or become tacky upon contact with petroleum solvents. Gloves would also be subject to adhesion and build-up of softened, solvent-activated rubber during ply application, and gloves would require frequent change, perhaps as frequently as a change after each tire is built, and the impact of such a procedure on the tire building process would be severe.

9. The inability of Goodyear to comply with the Dermal Contact Sections of the Benzene Standard in the tire building process is one critical example of compliance problems with the Sections. On information and belief there are several other areas of Goodyear's tire and rubber products manufacturing operations where Goodyear would be severely hampered by the Dermal Contact Sections.

10. Compliance with the Dermal Contact Sections of the Benzene Standard will cause Goodyear irreparable injury and will bring domestic tire production to a virtual standstill.

11. In reviewing the Benzene Standard, I have also given particular attention to the subsections relating to requirements for affixing caution labels to all containers of benzene and of products containing any amount of benzene, 29 CFR 1910.1028(k)(2)-(5) (the "Labeling Sections"). Compliance with the Labeling Sections will cause Goodyear irreparable harm.

12. It is not possible for Goodyear to adjust its manufacturing and shipping procedures relating to tires in order to comply with the Labeling Sections before the effective date of those Sections. Accordingly, compliance with the Labeling Sections of the Benzene Standard will effectively bring a halt to Goodyear's shipments of tires.

13. The Kelly-Springfield Tire Company ("Kelly-Springfield") and Lee Tire & Rubber Company ("Lee") are wholly-owned subsidiaries of Goodyear which are engaged in the manufacture and sale of tires and which employ more than 9,395 persons in manufacturing and related operations. On information and belief, compliance with the Dermal Contact Sections and Labeling Sections of the Benzene Standard by Kelly-Springfield and Lee would bring tire production at Kelly-Springfield and Lee to a standstill.

14. I further state that the above matters are based upon my personal knowledge except where otherwise noted, in which case they are based upon information and belief.

Dated this 8th day of March, 1978.

/s/ James R Sankey
JAMES R SANKEY

* * * *

AFFIDAVIT OF ROGER W. STRASSBURG OF THE B.F. GOODRICH COMPANY IN SUPPORT OF MOTION FOR STAY OF OSHA'S PERMANENT BENZENE STANDARD

I, Roger W. Strassburg, being duly sworn, do hereby state as follows:

1. I am currently employed by The B.F. Goodrich Company (Goodrich) at its corporate headquarters at Akron, Ohio in the capacity of Director of Environmental and Energy Affairs, a position I have held since 1977, prior to which for over five years I was Director of Environmental Affairs. The responsibilities of these positions include the coordination at the corporate level of all activities of Goodrich with respect to health, safety and environmental concerns. The organization of Goodrich includes various divisions involved in corporate support services, of which my function is a part, and several operating divisions. The domestic operating divisions are the Tire Division, the Engineered Systems Division and the General Products Division, all headquartered at Akron, and with which I am particularly involved, and the Chemical Division headquartered at Cleveland, Ohio.

2. I received a Bachelor of Science degree in Chemistry from Iowa State University in 1942 and a PhD degree in Organic Chemistry from the University of Minnesota in 1950. I joined Goodrich in 1951 and held various research and technical positions until 1969. In 1969 I was appointed Administrative Assistant to the President of Goodrich's Industrial Products Division (now a part of its Engineered Systems Division) and became Director of Environmental Affairs for Goodrich in 1973.

3. As part of my present duties I have the responsibility for assessing Goodrich's ability to comply with the permanent standard for occupational exposure to benzene (the "Benzene Standard") promulgated by the Occupational Safety and Health Administration (OSHA) as CFR Sections 1910.1028 at 43 *Federal Register* 5917, et seq on February 10, 1978. While my responsibilities ex-

tend to coordination of all Goodrich activities in connection with the Benzene Standard, including those of the Goodrich Chemical Division, my physical proximity to the headquarters of the Tire, Engineered Systems and General Products Division has led to my personal concentration on the activities of these Divisions. The effect of certain provisions of the Benzene Standard on the operations of the Goodrich Chemical Division is detailed in the Affidavit of Robert A. Krueger of Goodrich Chemical Division in support of Motion for Stay of Permanent Benzene Standard accompanying this document.

4. I have carefully reviewed OSHA's summary of the Benzene Standard and the standard itself as published in the Federal Register. I have particularly reviewed the section of the Benzene Standard dealing with dermal (and eye) contact with "liquid benzene", 29 CFR 1910-.1028(c)(2) and (h), (Dermal Contact Sections) and those dealing with labeling products containing "any amount" of benzene, 29 CFR 1910.1028(K)(2)-(5), (Labeling Sections). In connection therewith I have sought the counsel and advice of professional Goodrich personnel in both the corporate support services and operating divisions of Goodrich including personnel involved in the areas of industrial hygiene, purchasing, analytical sciences, law, manufacturing and marketing.

5. The information set forth herein is based on my personal knowledge and on information supplied to me by such persons.

6. Goodrich's Tire Division manufactures passenger, truck, aircraft, farm, industrial and related types of tires at manufacturing plants located at Woodburn, Indiana (near Fort Wayne); Miami, Oklahoma; Tuscaloosa, Alabama; Oaks, Pennsylvania and Akron, Ohio (non-passenger tires only). Collectively, more than 6,000 persons are employed at these plants in tire manufacturing and related operations.

7. An essential part of the tire building process is the attachment and adhesion of layers (plies) of uncured rubber compound coated on fabric, one to the other. In order to do this it is necessary that workers apply with a "swab" to the uncured rubber compound a small portion of organic solvent which has sufficient rubber solvation ability to impart tackiness to the plies and promote the adhesion. Application of the solvent to enable "unsticking" of plies improperly positioned at the tire building drums is also required, especially with larger sized tires of more complex construction, since precise positioning of the plies is critical in all tires for tire uniformity and compliance with safety standards. The liquid organic solvent must also, of course, have sufficient volatility characteristics to allow a rapid drying rate after application and thus prevent undue delays in the tire building operation.

8. Goodrich has been aware for some time of the health effects of benzene vapors in the workplace and has adapted work practices and controls such as to reduce the airborne concentration of benzene to the lowest feasible level. One of the most significant steps taken has been to procure organic liquid solvents for use in the tire building operation containing such a very low concentration of benzene that the airborne concentration of benzene vapor in the workplace will not exceed 1 part benzene per million parts of air (1 ppm) as an 8 hr. time weighted average (TWA).

9. On May 27, 1977 OSHA proposed a permanent standard for occupational exposure to benzene incorporating the 1 ppm TWA airborne exposure limitation. (42 FR 27452, et seq). However, the proposed standard specifically did not apply to "work operations where the only exposure to benzene is from *liquid* mixtures containing 1% (0.1% after one year) or less of benzene by volume or the vapors released by these liquids." Since Goodrich had already discontinued the use of solvent containing more than 1% benzene in its tire building operations, it submitted only a few comments on the proposed standard. It did not, because of the exemption, specifically address the dermal contact provisions of the proposed standard (which prohibited dermal contact with liquids containing more than 1% of benzene).

10. The Benzene Standard as promulgated removed the exemption. Its Dermal Contact Sections prohibit skin contact with any "liquid benzene" and the definition of

benzene, as well as the "preamble" description, indicate that liquid solvents containing any amount of benzene are included. Goodrich thus had no opportunity to comment on the final Dermal Contact Sections and explain the impossibility of building tires in compliance with these Sections as set forth below.

11. Goodrich has made an extensive search for a source of a liquid solvent for use in tire building which would have the necessary characteristics and contain "no benzene" but has been completely unsuccessful. No solvent or mixture of solvents is available which has the required rubber solvation and volatility characteristics and at the same time is completely free of benzene.

12. In the tire building operation described, the application of the solvent to the rubber compound requires the use of the workers' hands, which despite all feasible work practice precautions inevitably come in contact for the short period until evaporation with some quantity of the liquid solvent. In addition, application of the solvent to the plies as they are positioned on the revolving drum of a tire building machine, despite feasible work practice precautions, produces some "splashing" of the solvent (containing some dissolved rubber) on the worker's clothing with at least a theoretical chance of slight penetration to the skin.

13. It is critical to the tire building operation that the worker applying the solvent retain his manual and movemental dexterity, unfettered by restrictive protective clothing. If the hands are covered by impermeable gloves (as is apparently contemplated by the protective clothing provision of the Dermal Contact Sections) the gloves become "sticky" and may themselves adhere to the rubber stock with attendant difficulties and delays in the operation, perhaps harm to tire quality, and even the possibility of a safety problem. Further, "skin tight" rubber gloves would themselves be attacked by the solvent.

14. For the reasons above, Goodrich will suffer irreparable harm if it were required to comply with the Dermal Contact Sections. It is not now technically feasible for tires to be built without some skin contact with some solvent containing some amount of benzene. New

technological changes in preventing dermal contact with solvent would at best significantly slow down the tire production operations, again resulting in irreparable harm to Goodrich.

15. My study of the record leading to promulgation of the Benzene Standard (which has not for lack of time been complete) leads me to believe that the Dermal Contact Provisions were adopted (and the proposed Standard changed in this respect) without indication that harmful health affects occur through skin absorption of benzene present in small amounts in other liquids. In fact, the preamble to the regulation states that the primary course of entry of benzene in man is through inhalation and that the effect of benzene contact on the skin is essentially unknown. The Benzene Standard through the "action level" provision for airborne benzene does not purport to achieve inhalation control to absolute *zero* (which, of course, is a concept rather than an attainable reality) but there is nothing akin to an "action level" with respect to skin contact and absolute zero absorption through the skin is mandated. Accordingly, I believe there would be no harmful health effects in permitting workers to build tires as described using solvent containing small amounts of benzene and that to require otherwise is completely arbitrary and irrational.

16. The Goodrich Engineering Systems Division manufactures a line of rubber fabricated articles including hose and belts of various types at plants located in Akron, Ohio; Marion, Ohio; Oneida, Tennessee; Elgin, South Carolina; Richmond, West Virginia and Grantsville, West Virginia, at which plants it employs approximately 3,000 workers. The processing and fabricating operations at these plants are such that skin contact with liquid benzene or liquid solvent containing benzene is avoided and the proportion of benzene contained in the materials processed and used is such that airborne benzene concentrations would be expected to be safely below the Standard's "action level".

17. The Goodrich General Products Division manufactures a line of finished and semi-finished rubber and plastic products including many "adhesive products" for use

by industry and the consumer at plants located in Akron, Ohio; Gloucester, Massachusetts; Marietta, Ohio; [illegible]on, Ohio; New Ulm, Minnesota; Salem, Indiana and San Mateo, California with employment of some 2,000 workers. Liquid solvents containing trace amounts of benzene are used in the adhesive products plant at Akron, Ohio and perhaps at other plant locations but again the operations do not involve skin contact with such solvents and the airborne benzene concentration would be expected to be safely below the "action level".

18. However, considering that traces of benzene are present in synthetic rubber and other materials (excluding again liquid solvents containing benzene), used at these plants, and that the Benzene Standard applies to all places of employment where "benzene" without limitation as to amount or form, is "handled or used" it cannot be said that any workplace of these Goodrich divisions is unaffected by the Benzene Standard.

19. Of particular concern are the Labeling Sections of the Benzene Standard as applied to containers of "all products containing *any amount* of benzene" in the workplace and when the containers of finished products and articles leave the employee's workplace. The Labeling Sections seem to require the "Caution-Cancer" label on "containers" for such products not only in the plants of Goodrich's Tire Division but also in plants of its Engineered Systems and General Products Divisions. This will result in irreparable harm to Goodrich in that workers may be led to assume that the benzene in the containers is released to the air in the workplace in concentrations above the "action level" and criticize the plant management for not indicating that the workplace is a "regulated area".

20. Further, the Labeling Sections as applied to the finished products leaving the workplace are not sufficiently objective for Goodrich to know which finished products should bear the label on containers and would cause Goodrich irreparable harm without affect on worker safety for the same reasons as detailed in the aforementioned Krueger Affidavit. Consider as an example what possible good it would do to place a "Caution-Cancer"

label on the wrapper of a tire as it leaves a tire factory simply because the tire is made inpart from a synthetic rubber containing benzene in the parts per million range and there is no specific assurance that the tire manufacturing operations have eliminated the benzene to the point where the tire contains "absolute zero" content of benzene.

Moreover, the line of adhesive products made by Goodrich's General Products Division is so vast and the customers thereof so numerous that I see no practical limits to the downstream effect of the Labeling Sections. Certainly it is virtually impossible for there to be complete compliance with the Labeling Sections, if interpreted literally, in the foreseeable future, and it is absolutely impossible for this to be accomplished by the March 13th effective date of the Standard.

/s/ Roger W. Strassburg
ROGER W. STRASSBURG

* * * *

AFFIDAVIT OF ROBERT E. RHEM OF THE GENERAL TIRE & RUBBER COMPANY IN SUPPORT OF MOTION FOR STAY

Robert E. Rhem, being duly sworn, deposes and says:

1. I am now, and have been since December 1, 1974, Vice President of Manufacturing, Tire Division for The General Tire & Rubber Company ("General"), an Ohio Corporation having its principal place of business located in Akron, Ohio. I have been employed by General for approximately twenty-nine (29) years in various capacities relating to the manufacture of tires for automobiles, trucks, and off-the-road equipment, and have previously served as Production Manager for General's tire plant in Akron, Ohio and as Plant Manager of General's tire plant in Mayfield, Kentucky. I am personally familiar with all phases of the production processes utilized by The General Tire & Rubber Company in the manufacture of tires.

2. As Vice President of Manufacturing, Tire Division, I am directly responsible for the operations of six (6) tire manufacturing plants owned by General and operated within the United States. These manufacturing facilities are located in Akron, Ohio; Bryan, Ohio; Charlotte, North Carolina; Mayfield, Kentucky; Mt. Vernon, Illinois; and Waco, Texas. In addition, I am directly responsible for General's two (2) manufacturing facilities engaged in the production of tread rubber and rubber components, paints and cements for the tire recapping industry, which plants are located in City of Industry, California and Macon, Georgia, and General's facility in Barnesville, Georgia, which manufactures and processes tire cord materials for our tire production operations. These manufacturing operations combined employ more than 8,130 persons in manufacturing and related operations, and directly contribute to the local economy in seven (7) different states. I am personally familiar with the manufacturing operations at each of these production locations.

3. I have read and I am familiar with the Occupational Safety and Health Administration's permanent standard

for regulation of exposure to benzene in the work place (29 CFR 1910.1028, 43 *Federal Register* 5917, February 10, 1978). I have reviewed the provisions of the standard with various knowledgeable individuals within our manufacturing and technical organizations, and presently believe that compliance with most of the provisions of the standard, while difficult, will be attainable.

4. I have also read and reviewed the requirements of the standard relating to dermal and eye exposure 29 CFR 1910.1028(c) (2), protective clothing and equipment 29 CFR 1910.1028(h), and labeling 29 CFR 1910.1028(k) (2). I am informed and personally believe that as these provisions are presently written, The General Tire & Rubber Company will be unable to continue to manufacture tires and at the same time, comply with the above regulations. General will suffer irreparable harm if these provisions are not stayed pending review of the standard.

5. Petroleum-based solvents are essential to the tire manufacture process. Petroleum-based rubber solvents are used to "freshen" or tackify the surfaces of the rubber compounds. The construction of tires involves the assembly or attaching together of various rubber components and plies or layers of material into a finished "green" or uncured assembly. During the assembly process, which is performed on a rotating building drum, solvent is applied with a swab to each tire ply and other component surfaces to insure proper adhesion and maintain components in a fixed position during completion of the building operation. Precision placement of components, and maintenance of components placement during subsequent operations, are critical to tire uniformity and compliance with federal tire safety standards.

6. Placement and fitting of components during assembly is a skilled, manual operation. The tire builder's hands are in constant contact with surfaces that have been activated by solvents containing some amount of benzene. In addition, when the rotating building drum is turned, excess amounts of solvent may be thrown off in the process, and may again come in contact with the tire

builder. General knows of no means by which this skilled assembly process could be automated to eliminate this skin contact with solvents containing some benzene, nor does General know of any suitable substitute solvent for the tire building process.

7. In addition to the tire building process outlined above rubber solvents containing trace amounts of benzene are necessary, critical to, and used in other operations within the tire manufacturing facilities. Rubber solvents are used in the preparation of cements which are applied to various components and, by necessity, these components are handled by employees during the transfer and building and manufacturing processes. Solvents are also necessary in the area of tire repair, where it is necessary to soften or retackify "green" or uncured as well as cured tires in order to make permitted repairs during the manufacturing process. These repairs are of necessity critical, skilled, manually performed operations. Rubber solvents are also used in the retreading and recapping industry, as are cements manufactured using solvents containing trace amounts of benzene, and these operations again require substantial handworking in contact with surfaces treated with solvents. Finally, but not necessarily by way of exclusion, petroleum-based solvents are used in inside and outside "green tire" lubricants applied to the uncured tires prior to curing.

8. Petroleum solvents suitable for tire building and related tire manufacturing operations do contain trace amounts of benzene as an impurity. General purchases these rubber solvents from various manufacturers who have advised the Company's purchasing representative that suitable solvents containing no benzene are not commercially available. After promulgation of the proposed benzene standards, General requested its suppliers to certify that suitable rubber solvents would contain 1% or less of benzene, and General changed its solvent specification to include that minimum requirement. This change in specification was made in consideration of the proposed standard on Occupational Exposure to Benzene 42 *Federal Register* 27452, May 27, 1977, which provided in 29 CFR 1910.1028(a) (ii) an exclusion "to work operations where the only exposure to benzene is from liquid mixtures containing 1% (0.1% after one year from the effective date of the standard) or less of benzene by volume, or the vapors released from these liquids." Solvents in use by General conform to these specifications, but due to the nonexistence of commercially available benzene-free suitable solvents, and due to OSHA's elimination of the one percent (1%) exclusion in this permanent standard, dermal contact with liquids containing benzene cannot be prevented if tire manufacturing is to continue at the General Tire & Rubber Company.

9. I am informed and believe that dermal or eye contact with solvents containing benzene cannot be prevented through the use of protective clothing and eye and face protection. Building, repair, and other skilled manual operations involved in the tire manufacturing process require precision which would be hampered by the use of gloves, if solvent impervious gloves were available which would not dissolve upon contact with rubber solvents and would not become tacky upon contact with rubber cements manufactured with such solvents. General knows of no such gloves or other impervious garments available to the industry. In addition, due to the necessity of using rotating building drums and other forms of moving machinery, the use of protective garments, if available, would create additional safety hazards, and the added risk of injury due to the possibility of protective garments being caught in moving machinery, or due to the hampering of employee's reflexes and dexterity necessary to operate equipment and manufacture tires in a safe manner. On information and belief, production of tires at the General Tire & Rubber Company would be seriously hampered and drastically reduced by the use of such protective garments in order to avoid dermal contact with solvents containing only trace amounts of benzene.

10. For all of the foregoing reasons, compliance with the dermal contact provisions of the standard will cause The General Tire & Rubber Company irreparable injury and bring critical, precision manufacturing in the field of domestic tire production to a halt. For the same reasons,

continued production of tires within The General Tire & Rubber Company would, of necessity, have to be performed utilizing currently known and proven methods, processes and materials, including suitable solvents, thereby forcing General to be in non-compliance with 29 CFR 1910.1028(c)(2) and (h) if the Company is to remain operative in the business of manufacturing tires. It is not possible for General to remain in production and comply with these provisions of the standard at the same time.

11. In reviewing the Benzene Standard, I have also given particular consideration to 29 CFR 1910.1028(k)(2) relating to labeling requirements. This section requires that the employer assure that caution labels are affixed to all containers of benzene and of products containing any amount of benzene. Compliance with this section will cause General irreparable harm.

12. It is not possible for General to comply with such requirement before the effective date of that section, since sufficient time has not been allowed to obtain and affix the vast number of such labels as may be required now that the permanent standard has defined benzene to include all "mixtures of liquids containing benzene". This requirement, in the absence of the prior one percent (1%) exclusion of the proposed standard and Temporary Emergency Standards, will require the Company to review and perhaps analyze the contents of a vast array of solvents, cements, inks, adhesives, and other liquid chemicals used in its manufacturing, laboratory and maintenance operations. In addition, compliance is rendered impossible due to OSHA's total failure to adequately define the terms "containers of benzene" or "products containing any amount of benzene". While OSHA admittedly has authority to regulate hazards in the work place, the employer should not be required to engage in sheer speculation as to what parts or portions of its manufacturing equipment and facilities constitute "containers of benzene", especially in view of the numerous solvents, cements, and adhesives containing only trace amounts of benzene that are used in the rubber industry in both manual and automated application processes. In addition, since the term "products containing any amount of benzene" has not been limited in any way to solid, liquid,

or gaseous products, it is conceivable, although obviously unreasonable, that such labeling provision could be interpreted to include even solid products such as tires and related rubber goods which may contain within their solid form trace amounts of benzene as a contaminant. In the absence of a stay as to this labeling provision, General cannot comply with this portion of the regulation due to the reasons and uncertainties set forth above.

13. I further state that the above matters are based upon my personal knowledge, or upon information supplied to me by competent and knowledgeable persons upon whom I rely, and are true to the best of my knowledge.

/s/ Robert E. Rehm
ROBERT E. REHM

* * * *

AFFIDAVIT OF ROY N. JOHNSON OF THE GENERAL TIRE & RUBBER COMPANY IN SUPPORT OF MOTION FOR STAY

Roy N. Johnson being first duly sworn, deposes and says:

1. I am now and have been Corporate Director of Safety and Health for The General Tire & Rubber Company of Akron, Ohio for the past four years. In addition, I have twenty-two (22) years of experience in the field of Safety Engineering and Employee Health, directly related to the Rubber and Plastics Industries.

2. In my present position, I have the responsibility for establishing Company policy and procedure which will assure a safe and healthy working environment for all employees of The General Tire & Rubber Company. While my job encompasses said areas of Safety and Health for all divisions of the Corporation, this affidavit seeks to explain those Provisions of the permanent Standard which will adversely effect the operations of our Industrial Products and Chemical/Plastics divisions, as differentiated from our Tire Division.

3. I have read and am familiar with the permanent Standard of the Occupational Safety and Health Administration for the regulation of occupational exposure to benzene, 29 CFR Section 1910.1028, published in 43 *Federal Register* 5917, February 10, 1978. I have particularly reviewed the Sections relative to dermal and eye contact and protective clothing.

4. Because the Standard does not specify any lower permissible limit of benzene as a contaminant in petroleum-based solvents, compliance in many of our operations will be impossible, short of total shutdown. Thereby, irreparable harm will result to The General Tire & Rubber Company.

5. Specifically, in our Industrial Products and Chemical/Plastics divisions, solvents containing trace amounts of benzene are used in many hand-contact operations. These include, but are not limited to: polyester and styrene unloading and transfer; parts and reactor cleaning; roll coating; printing operations; and, manufacture and use of solvent-based adhesives.

6. We have been informed by our suppliers that it is virtually impossible to remove all traces of benzene from commercial solvents used by our industry.

7. Compliance with the present Standard would require such equipment as imeprvious gloves, respirators and eyeglasses. The net effect would make it impossible to assemble tennis balls, assemble bushings and mold gaskets. These are precision operations which necessitate direct hand contact.

8. In my review of the Benzene Standard, I have given special consideration to 29 CFR Section 1910.1028(k)(2), which provides for labeling requirements. This provision requires that caution labels be affixed to all containers of benzene and of products containing any amount of benzene. If General Tire is required to abide by the letter of this section, irreparable harm will result.

9. Because of the severe requirements, it is impossible to comply with such labeling requirements within the stipulated time period. If taken to its logical conclusion, we could be required to label all products in our work environment which could contain mere traces of benzene contaminates in their solid form such as latex materials, coated vinyl fabrics and rubber products being shipped out for sale. It is our belief that this aspect of the Standard exceeds the authority of OSHA.

10. I further state that the above matters are based upon my personal knowledg or upon information supplied to me by competent and knowledgeable persons upon whom I rely, and are true to the best of my knowledge and belief.

/s/ Roy N. Johnson
ROY N. JOHNSON.

[Amend. Exh. 32-F-3]

* * * *

SUPPLEMENTARY AFFIDAVIT
OF JAMES R. SANKEY OF
THE GOODYEAR TIRE & RUBBER COMPANY
IN SUPPORT OF MOTION FOR STAY

STATE OF OHIO)
) ss.
COUNTY OF SUMMIT)

JAMES R. SANKEY, being duly sworn, deposes and says:

1. I am now and have been for the past three years Director of Domestic Tire Production for The Goodyear Tire & Rubber Company ("Goodyear"), an Ohio corporation with its principal offices located in Akron, Ohio. I have been employed by Goodyear for thirty five (35) years in various capacities relating to the manufacture of tires for automobiles, trucks and other wheeled vehicles and have managed tire plants in Akron, Ohio; Union City, Tennessee; and New Delhi, India. I am personally familiar with all aspects of the process of manufacturing automobile, truck and related type tires.

2. Goodyear is the world's largest manufacturer of tires and produces more tires in the United States than any other tire producer.

3. As Director of Domestic Tire Production, I am directly responsible for the operations of eight (8) domestic tire manufacturing plants owned and operated by Goodyear. These facilities are located in Akron, Ohio; Danville, Virginia; Gadsden, Alabama; Jackson, Michigan; Los Angeles, California; Madisonville, Kentucky; Topeka, Kansas; and Union City, Tennessee. Collectively, these facilities employ more than 15,695 persons in manufacturing and related operations. I am personally familiar with all aspects of the operations at each of these facilities.

4. I have read and am familiar with the permanent standard of the Occupational Safety and Health Administration for the regulation of occupational exposure to benzene (29 CFR 1910.1028, 43 *Fed Reg* 5917, Feb 10, 1978) (the "Benzene Standard"). I have particularly reviewed the sections of the Benzene Standard dealing with dermal and eye contact with liquid benzene, 29 CFR 1910.1028(c)(2) and (h) (collectively referred to as the "Dermal Contact Sections"). I am also familiar with OSHA's announced intention to stay enforcement of the Benzene Standard where the sole exposure is from mixtures containing 0.1% or less of benzene.

5. Even if the Benzene Standard's application is thus restricted, Goodyear is unable to manufacture tires in compliance with the Dermal Contact Sections of the standard, and Goodyear will, therefore, suffer irreparable harm if the Dermal Contact Sections of the Benzene Standard are not stayed.

6. As stated in my prior Affidavit, dated March 8, 1978, the use of petroleum solvents is essential to the manufacture of tires. As described fully in my first Affidavit, the tire building process necessarily involves manual contact by the builder with the surface of the tire which has been activated by solvents containing benzene. This manual contact involves dermal contact, since gloves or other protective hand coverings are neither suitable nor feasible in tire building.

7. The petroleum solvents suitable for tire building contain trace amounts of benzene as an impurity. Goodyear has requested all major suppliers of petroleum solvents to provide Goodyear with solvents which do not contain any amount of benzene. These suppliers have advised Goodyear that it is not feasible to remove all the benzene from petroleum solvents used in the construction of tires. Also, despite Goodyear's requests, solvent suppliers have refused to assure or guarantee any fixed, low levels of benzene content. Therefore, Goodyear is unable to assure itself that it will receive solvents containing 0.1% or less of benzene.

8. Therefore, Goodyear cannot comply with the Dermal Contact Sections of the Benzene Standard, even if OSHA proceeds to stay enforcement of the standard as to exposures solely from mixtures containing 0.1% or less of benzene. Goodyear will suffer irreparable injury if the Dermal Contact Sections are not stayed, in that Goodyear's domestic tire production will be brought to a virtual standstill.

9. The Kelly-Springfield Tire Company ("Kelly-Springfield") and Lee Tire & Rubber Company ("Lee") are wholly-owned subsidiaries of Goodyear which are engaged in the manufacture and sale of tires and which employ more than 9,395 persons in manufacturing and related operations. On information and belief, compliance with the Dermal Contact Sections and Labeling Sections of the Benzene Standard by Kelly-Springfield and Lee would bring tire production at Kelly-Springfield and Lee to a standstill.

10. On information and belief, there are several other areas of Goodyear's tire and rubber products manufacturing where Goodyear will be severely and irreparably harmed if the Dermal Contact Sections are not stayed. Among them are the building of motorcycle tires, v-belts, conveyor belts and hosing, all of which operations involve the use of rubber solvents as tackifying agents in the building process and which will involve some degree of dermal contact with such benzene-containing solvents. These operations are conducted in six (6) domestic plants.

11. I further state that the above matters are based upon my personal knowledge except where otherwise noted, in which case they are based upon information and belief.

Dated this 28th day of March, 1978.

/s/ James R. Sankey
JAMES R. SANKEY

[AMEND. EXH. 32-F-3]

* * * *

AFFIDAVIT OF ROBERT W. LAUNDRIE OF THE GENERAL TIRE & RUBBER COMPANY IN SUPPORT OF MOTION FOR STAY

Rcbert W. Laundrie, being duly sworn, deposes and says:

1. I am now, and have been since 1971, Manager of Ecology, Safety & Health Engineering for the Chemical/Plastics Division of the General Tire & Rubber Company ("General"), an Ohio Corporation having its principal place of business located in Akron, Ohio. I have been employed by General for 22 years in various capacities in the chemical and plastics industry, and I am personally familiar with all phases of that Division's manufacturing operations, including the operations involved in the manufacture of tennis balls.

2. The General Tire & Rubber Company is the largest producer of tennis balls in the United States, with domestic manufacturing plants located in Phoenix, Arizona and Jonesboro, Arkansas, and with total employment at both locations being approximately 500 persons.

3. I have read and I am familiar with the Occupational Safety and Health Administration's permanent standard for regulation of exposure to benzene in the work place (29 CFR 1910.1028). I have reviewed the standards and believe that compliance with most provisions, while difficult, will be attainable.

4. I have specific concern, however, with the requirement of the standard respecting dermal and eye exposure to liquids containing benzene (29 CFR 1910.1028(c)(2)), as those standards relate to the manufacture of tennis balls. I am also familiar with OSHA's announced intention to consider modification of the standard so that it would be applicable to only liquids containing greater than .1% benzene by volume. I am, however, informed and personally believe that as this provision is presently written, The General Tire & Rubber Company will be

unable to continue to manufacture tennis balls, and at the same time, comply with the above regulations. In addition, this situation will not be improved by OSHA's proposed amendment, and in either case, General will suffer irreparable harm.

5. Petroleum-based solvents are essential to the tennis ball manufacturing industry, as they are a necessary ingredient in the cement mixtures used to assemble the various tennis ball's components. Benzene is not a necessary element in tennis ball manufacture, but it exists in trace amounts as a contaminant in the petroleum-based solvents presently available to our manufacturing plants.

6. Though efforts have been made to obtain a reliable source of benzene-free solvents, our suppliers are not presently able to supply solvents in a benzene-free state, or if available, not presently able to supply our production needs of approximately 19,000 gallons per month on a repetitive basis, totally benzene-free.

7. Solvent suppliers presently serving our tennis ball manufacturing facilities advise that they can deliver solvents containing .3% to .5% benzene on a repetitive basis, in sufficient quantities to meet production requirements.

8. Solvents presently available in sufficient quantities to maintain production at our tennis ball facilities cannot meet either the present or proposed OSHA standards for benzene content.

9. While most of the tennis ball production process is highly automated, a certain amount of hand transfer is required, and a potential for skin contact with wet cements containing trace amounts of benzene exists during these transfer operations.

10. Due to the tacky conditions of the components, and their thin and flexible condition, accurate and efficient handling cannot be accomplished wearing heavy gloves, and no known thin rubber gloves are currently available that would not react adversely with the wet rubber cements or adhesives. While we are presently exploring the availability of barrier creams or other directly applied solutions that might protect against

such exposures, none are presently known to be effective; and further time for analysis and experimentation will be necessary in this area.

11. While a possible exposure to trace amounts of benzene does exist, the exposure potential appears to be limited to approximately 40 to 45 employees out of our entire operations. A review of available medical records from 1976 to present reveals only one reported skin disorder which may or may not have arisen as a result of contact with cements containing benzene; and therefore, no apparent dermatitis hazard is known to result from these potential exposures.

12. For the foregoing reasons, General will be unable to comply with either the present or proposed OSHA standards for skin contact with liquids containing benzene, and still continue tennis ball manufacturing operations. While solutions to these problems are no doubt available in the future, our present technology will not permit compliance and production to co-exist; and therefore, in the absence of a stay of the standard, General will suffer irreparable harm.

13. I further state that the above matters are based upon my personal knowledge, or upon information supplied to me by competent and knowledgeable persons upon whom I rely, and are true to the best of my knowledge and belief.

/s/ Robert W. Laundrie
ROBERT W. LAUNDRIE

* * * *

[Amend. Exh. 32-A-3]

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

Nos. 78-1257, 78-1253, 78-1486, 78-1676, 78-1677

AMERICAN PETROLEUM INSTITUTE, ET AL., PETITIONERS,

v.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION; UNITED STATES DEPARTMENT OF LABOR; DR. EULA BINGHAM, ASSISTANT SECRETARY OF LABOR; AND RAY MARSHALL, SECRETARY OF LABOR, RESPONDENTS,

INDUSTRIAL UNION DEPARTMENT, INTERVENOR.

SECRETARY OF LABOR'S SUPPLEMENTAL OPPOSITION TO PETITIONERS REQUEST FOR STAY PENDING JUDICIAL REVIEW

* * * *

[67] In like fashion, various rubber manufacturers have appeared here, arguing that they cannot comply with the personal protective equipment sections of the standard absent the 1% exemption because the manufacture of tires requires the application of solvents containing benzene by hand, and rubber gloves cannot be used because they become tacky. These petitioners also participated in the rulemaking proceeding with full knowledge that within one year at best the agency was proposing to include these solvents in the standard. Yet their problem with personal protective equipment compliance raised here was never raised before the agency. Like Chemical Specialties, it is disingenuous, to say the least, for these companies now to come into court and seek relief for the results of their own inaction. As indicated in the agency's response to their petition for administrative review, it appears that they have, even though at a very late date,

advanced a real problem which is probably appropriately dealt with through the temporary variance procedure dealt with *infra* at 64-65. Again, an employer may always prove that it is simply impossible for him to comply with a standard in the context of an enforcement proceeding and, as is the case with Chemical Specialties, to the extent citations do issue, an employer's good faith attempts to comply will of course mitigate any penalty which might be proposed.

[Amend. Exh. 32-F-4]

* * * *

AFFIDAVIT OF N. A. DAIGLE
OF THE FIRESTONE TIRE & RUBBER COMPANY
IN SUPPORT OF MOTION FOR STAY

STATE OF OHIO)
) SS
COUNTY OF SUMMIT)

I, N. A. Daigle, being duly sworn, upon oath depose and state as follows:

1. I am currently employed by The Firestone Tire & Rubber Company ("Firestone") as Manager of North American Tire Plant Laboratories at Firestone's corporate headquarters in Akron, Ohio.

2. The statements of fact set forth herein are true and correct to the best of my knowledge, information and belief.

3. Firestone has conducted preliminary tests to determine the effect on adhesion from the use of barrier creams in tire building operations to prevent any possible absorption of benzene through the skin. Firestone has no actual knowledge of the protection provided by such creams, but Firestone tested the barrier cream product reported to provide the best protection against possible absorption of benzene through the skin.

4. Tests were conducted by applying this cream to the hands, working the cream into the hands by rubbing, wiping off the excess cream with a dry cloth, and then handling the surface of tire stock with the finger tips. A standard one inch adhesion pad was prepared to determine the effect on adhesion from this use of this barrier cream. These test results indicate a 60% loss of adhesion when the cream was applied in the above manner.

5. Additional tests were conducted applying this cream directly to the surface of the tire stock. This condition

could occasionally occur in tire building, particularly from an individual not removing an excess of cream before handling the surface. A standard one inch adhesion pad was prepared to determine the effect on adhesion from this use of this barrier cream. Such tests indicated a 100% loss of adhesion.

6. Adhesion is essential in the tire building process and a 60% loss of adhesion is entirely unacceptable. Such a loss of adhesion would result in tire separation and an unsafe tire.

/s/ N. A. Daigle
N. A. DAIGLE

* * * *

SECOND SUPPLEMENTAL AFFIDAVIT OF ROGER W. STRASSBURG OF THE B. F. GOODRICH COMPANY IN SUPPORT OF MOTION FOR STAY OF OSHA'S PERMANENT BENZENE STANDARD

STATE OF OHIO)
) SS.
COUNTY OF SUMMIT)

I, ROGER W. STRASSBURG, being duly sworn, do hereby state as follows:

1. On March 8, 1978, I executed for this proceeding an Affidavit in Support of Motion to Stay and on March 29, 1978, I executed a Supplemental Affidavit in Support of Motion to Stay.

2. Paragraph 13 of my March 8 Affidavit and paragraph 3 of my Supplemental Affidavit show the practical impossibility of building tires using necessary benzene-containing rubber solvent while protecting the tire builders' hands with gloves. Since the date of my Supplemental Affidavit I have received a Technical Document from the Goodrich Tire Division reporting on the tests conducted on "Use of Gloves During Tire Construction" with which was enclosed a copy of an article from the February, 1978 issue of the American Industrial Hygiene Association Journal authored by Sansone and Tewari entitled "The Permeability of Laboratory Gloves to Selected Solvents". These documents are attached hereto as Exhibits A and B respectively. From these documents it is apparent that there are no available gloves which are satisfactory for use by tire builders to prevent skin contact with the rubber solvent. The only glove material not permeable to benzene containing solvent is polyvinyl alcohol (PVA) and it is permeable to water (see last column of last line of Table 1 of Exhibit B). Hence PVA gloves would be attacked from the inside by the water from the "hand sweating" which always occurred.

3. In paragraph 14 of my March 8 Affidavit I pointed out that the preamble to the Benzene Standard states that the *primary* cause of entry of benzene in man is through inhalation; that the Standard provides a permissible exposure limit (PEL) of airborne inhalable benzene of 1 ppm TWA over 8 hours (twice the "action level") for this *primary* mode of entry and that the Standard provided nothing akin to an "action level" or PEL with respect to a *possible* secondary mode of entry of benzene in man through skin absorption. In paragraph 5 of my Supplemental Affidavit I pointed out that the existing literature on benzene absorption through the skin related only to liquid benzene (i.e., essentially 100% benzene) not to liquid mixtures containing small amounts of benzene (rubber solvent with 0.1% up to 1% benzene). These considerations, coupled with the recent OSHA proposed exclusion of liquid mixtures containing 0.1% or less benzene, have led me first to seek to determine the relationship between entry of benzene in man through inhalation of airborne benzene at the PEL versus *absolute maximum possible entry through skin absorption* from a 0.1% benzene solvent and secondly to seek to determine the maximum *probable entry by skin absorption* from rubber solvent using the existing literature as to entry by skin absorption from essentially 100% benzene. I have made such determinations as accurately as I can in the limited time available and the results are set forth below.

4. Considering first entry of benzene in man through inhalation, I find from the reference book "Industrial Hygiene and Toxicology" by Patty, Vol. 1, 2nd Edition, page 151, that a worker engaged in moderately heavy work (typical of a tire builder) will breath in 9600 liters of air in an 8 hour working day. If this air contains the PEL of 1 ppm of benzene, that is 3 mg per m^3, the total amount of benzene entry is 9.6 x 3 or 28.8 mg over the 8 hour period.

5. Consider now the absolute maximum possible entry of benzene by skin absorption in respect to a tire builder's use of 0.1% benzene rubber solvent. A tire builder engaged in applying the "first step tread over sidewall", a

typical tire building operation using rubber solvent, will in an 8 hour day have the palm of one hand in the rubber solvent approximately 30 times. If the whole hand is dipped in rubber solvent, 2.64 grams of solvent will remain on the hand after the dip, as determined by accurately weighing a container of solvent before and after the dip. Thus, the *absolute maximum possible* amount of benzene which could enter the tire builder from the solvent in an 8 hour day is 2.64 divided by two (the palm being one-half of the whole hand) times 0.001 (0.1% benzene in solvent) times 30 which equals 39.6 mg benzene.

6. From paragraphs 4 and 5 above, it is apparent that total entry of benzene into the body of a tire builder through skin absorption would be of the same magnitude as total entry of benzene through inhalation at the PEL even if *it be assumed that absolutely all the benzene contacted by the hands were absorbed.* This assumption is obviously false since it takes no account whatever of the fact that the bulk of benzene containing-solvent in contact with the worker's hand is continuously and rapidly being evaporated so that only a small portion of the total benzene which originally contacts the hands could possibly be absorbed through the skin. This leads to a calculation of the *probable maximum* entry through absorption of benzene in rubber solvent based on the existing literature as to absorption from essentially 100% benzene.

7. The article by Hanke, Dutkiewicz and Piotrowski entitled "Absorption of Benzene Through the Skin in Man" appearing in the Institute of Industrial Toxicology of the Institute of Labor Health, Lodz, Poland, of record in the proceeding leading to the Benzene Standard, describes experiments on determination of maximum actual absorption of benzene in man as a result of direct contact with essentially 100% liquid benzene. The statement is made (p. 16 of translation for OSHA) that for an area of both palms of man's hands of 600 cm^2, the maximum amount of *actual* benzene absorption in the course of 8 hours "*might be about 2000 mg*". Relating 2000 mg with both palms in 100% benzene to one palm in 0.1% benzene, the value for *maximum actual benzene absorption* by tire builder's use of rubber solvent with 0.1% benzene would be, on a linear basis, 0.001 x 2000 mg divided by 2 or only 1 mg as against the *maximum possible benzene absorption* from paragraph 5 above of approximately 40 mg. On the same linear basis, if rubber solvent containing 1% benzene were used, maximum actual benzene absorption from skin contact would be 10 mg and this value is still only one-third of the approximately 30 mg from inhalation at the PEL.

8. I recognize that I have no scientific information to establish the linear relationship basis in my calculations in paragraph 7. However, in the light of the testimony of Dr. Howard Maibach at the OSHA hearings to the effect that the Hanke, et al experiments, through use of the glass plate, had *driven the benzene through the skin* to a much greater degree than would otherwise have been the case, I believe that any "under-estimation" due to my using the linear relationship is counterbalanced by the "over-estimation" inherent in the Hanke, et al study.

9. I conclude from the above that there would be no more actual absorption of benzene as a result of the skin contact involved in the tire building operation through use of rubber solvent containing up to 1% benzene than from inhalation of benzene at the PEL or even at the "action level". I further believe that insofar as it applies to skin contact in tire building operation the OSHA proposed "exemption" from the Benzene Standard of liquids containing 0.1% or less benzene could logically be applied to liquids containing more than 0.1% benzene up to even as much as 1% benzene, without harm to the health of tire builders.

10. I am aware that OSHA considers various skin conditions such as dermatitis, also to be a factor with respect to the dermal contact portions of the Benzene Standard. However, I believe it is well known that such conditions are by no means unique to benzene and apply equally to other hydrocarbons which dissolve "fats" and that, therefore, they are not properly a factor for consideration in fixing the percentage of benzene in liquid mixtures which

should be exempted from the dermal contact provisions of the Benzene Standard.

/s/ Roger W. Strassburg
ROGER W. STRASSBURG

[The following is the percentage-exclusion amendment and the accompanying statement of reasons, 93 Fed. Reg. 27962 (June 27, 1978)]

Title 29—Labor

CHAPTER XVII—OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, DEPARTMENT OF LABOR

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

Occupational Exposure to Benzene; Liquid Mixtures

AGENCY: The Occupational Safety and Health Administration, Department of Labor.

ACTION: Final rule.

SUMMARY: This document amends the recently issued occupational safety and health standard for exposure to benzene by: (1) Exempting from all the provisions of the permanent standard for benzene (29 CFR 1910.1028), for the first three years following the effective date of this amendment, liquid mixtures containing 0.5 percent or less benzene, and thereafter liquid mixtures containing 0.1 percent or less benzene; and (2) exempting from the labeling requirements liquid mixtures containing benzene which are already packaged and which contain 5.0 percent or less benzene. The amendments are in response to several petitions concerning the applicability of the benzene standard to liquid mixtures.

EFFECTIVE DATE: June 27, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. Gail Brinkerhoff, Office of Compliance Programs, OSHA, Third Street and Constitution Avenue NW., Room N3112, Washington, D.C. 20210, telephone 202-523-8034.

SUPPLEMENTARY INFORMATION: These amendments are issued pursuant to sections 4(b) and 6(b) of the Occupational Safety and Health Act of 1970 (the Act) (84 Stat. 1592, 1593; 29 U.S.C. 653, 655), the Secretary of Labor's Order No. 8-76 (41 FR 25059) and 29 CFR Part 1911. These amendments appear at 29 CFR 1910.1028(a)(2)(iii) and at 29 CFR 1910.1028(k)(2)(iii).

I. Background

Benzene is a naturally occurring constitutent of crude oil and national gas produced from underground reservoirs and surfacing through wells. There are approximately 630,000 wells in some 10,000 oil and gas fields in the U.S. (exhibit 29D1). One or more reservoirs underlies each of these oil and gas fields (exhibit 29f, p. 2). Since crude oil and natural gas vary in composition and physical properties from reservoir to reservoir (exhibit 29f, p. 2), the benzene content of the fluid at a particular oil or gas field may vary from well to well.

From the wellhead, the reservoir fluid is delivered by flow lines or gathering lines to separation facilities (exhibit 29D1) or field treatment plants (exhibit 29f, p. 4) where it undergoes a number of production treatment steps necessary to produce marketable crude oil, condensates and natural gas streams, as well as a variety of hydrocarbons (exhibit 29f, p. 4).

The benzene content of crude oil ranges from below detectable limits to greater than 1 percent (exhibit 29f, p. 3). Condensates produced from natural gas liquids present in both crude oil and natural gas (exhibit 29f, pp. 2-3) have a higher percentage of benzene than crude, with that percentage ranging from approximately 0.2 to 1.0 percent by volume (exhibit 29D1). The benzene in natural gas varies from 0 to about 4 percent (exhibit 29D1).

From the separation facilities or treatment plants, the crude oil, condensates and liquid and gaseous hydrocarbons are delivered to refineries either by waterway or by pipelines (exhibit 29D1; Comeaux). It is common practice for liquids from a number of fields to be combined

into one pipeline stream for transportation do refineries (exhibit 29D1); Comeaux, p. 4).

At the refineries, the crude oil and field condensate liquids are stored in holding tanks prior to processing (exhibit 29f, p. 5). Typical petroleum refining processes are many. Not all refineries have all of these processes since there is specialization, such as fuels, lubes or petrochemical operations, within refineries (exhibit 29f, p. 5). At all refineries, however, additional benzene is generated during refining by catalytic cracker, reformer and coker operations (exhibit 29f, p. 2; tr. 284).

Petroleum refined products are many and their benzene content varies according to the content of the crude taken into the refinery, the nature or the efficiency of the refining process, and the balance of product demands on the refinery. Thus, the benzene content of product streams within a single company may vary from refinery to refinery or within a single refinery from year to year. The same product from different refineries or at different times from the same refinery, consequently, may have a different benzene content (tr. 284-5). Motor gasoline ranges from 1 to 3 percent benzene by volume (Bailey). Aviation gasoline, specialty naptha solvents and naptha-based, (type B) jet fuels may exceed 1 percent benzene concentrations. Heavier jet fuel (type A), light fuel oils and cutback asphalts may occasionally exceed 0.01 percent benzene. Petrochemical feedstock napthas and certain aromatics, such as toluene may contain up to 1 percent benzene (exhibit 29f, pp. 7-8). This petrochemical feedstock is used to produce ethylbenzene, styrene monomer, cumene, phenol, cyclohexane, and nitrobenzene.

Processed refined petroleum products are distributed through marketing channels, including bulk terminals and bulk plants, to consumers. Initial distribution from the refinery storage facilities may be by pipeline, barge, marine tankers, tank truck or tank car (exhibit 29f, p. 11). These refined products have numerous uses, such as fuels, extractants, processing aids, and solvents in paints, surface coatings, adhesives and pesticides, inks, etc. The benzene content of these products varies from less than

one-tenth to a few percent (tr. 284, comment 53, 58, 21, 35).

There are some substitutes for benzene; however, most of the solvent substitutes themselves contain benzene. As indicated below, the percentage of benzene in some substitutes may range up to 4 percent (18-45; tr. 304).

Benzene is also derived from coal. Recovery of coal-derived benzene, primarily as a by-product of the coking process in steel mills, accounts, however, for only 6 percent of the total U.S. production (43 FR 5918). The light oil, which is condensed from coke gases, contains up to 70 percent benzene. This light oil is distilled to produce benzene. Most light oil plants do not produce benzene but sell their light oil to petroleum refineries for further processing. Only 10 light oil plants do produce benzene and these sell it to other users.

II. History of Regulation

On February 10, 1978, a permanent occupational safety and health standard regulating occupational exposure to benzene was published in the Federal Register (43 FR 5918) as 29 CFR 1910.1028. (A correction document was published on March 31, 1978, at 43 FR 13561). This standard required employers to take prescribed measures to control employee exposure to benzene. The standard applied to each place of employment where benzene in any quantity was produced, reacted, released, packaged, repackaged, stored, transported, handled or used. The standard contained no percentage exclusion and applied to work operations involving any amount of benzene.

The permanent benzene standard was developed, pursuant to sections 6(b) and 6(c) of the act, after exhaustive rulemaking which commenced with publication on May 3, 1977 of an Emergency Temporary Standard for Occupational Exposure to Benzene (42 FR 22516). The emergency temporary standard exempted liquid mixtures containing 1 percent or less of benzene volume, or the vapors released from these liquids. On May 27, 1977, OSHA published a proposed permanent standard to control occupational exposure to benzene (42 FR 27452).

This proposed standard would also have exempted work operations where the only exposure to benzene was from liquid mixtures containing 1.0 percent (0.1 percent after 1 year) or less of benzene by volume, or the vapors released from these liquids. On the basis of the record developed in the rulemaking on the permanent benzene standard (Docket H-059), OSHA concluded that there was no consistent predictable relationship shown between the percentage of benzene in a liquid mixture and the resultant airborne exposure to benzene and that, consequently, the percentage proposed exclusion could not be supported (43 FR 5942).

After promulgation of the final standard which contained no percentage exclusion, OSHA received requests from several employers and employer groups for an administrative stay of the standard or other relief from the provisions of the standard as it applied to work operations where exposure to benzene resulted from liquid mixtures containing small or "trace" amounts of benzene. For reasons set forth in its notice (43 FR 12890, March 28, 1978), OSHA proposed to amend the benzene standard to exclude from its coverage work operations where exposure to benzene is from liquid mixtures containing 0.1 percent or less benzene or the vapors from such liquids. Skin contact with such mixtures would also be excluded from the standard. Pending final action on this proposed amendment, OSHA stayed the application of the provisions of the benzene standard to such work operations (43 FR 12891). Since this stay was immediately effective, OSHA commenced an expedited rulemaking to resolve the percentage exclusion question so that employers could know which, if any, of their operations were excluded from the permanent benzene standard. (A correction document was published on April 4, 1978, at 43 FR 14071). On April 28, 1978, OSHA published a notice of hearing on the proposed amendment (43 FR 18215). The public hearing on this proposal was held on May 23 and May 24 at Washington, D.C. Approximately 40 individuals participated at this hearing. Furthermore, more than 100 comments, arguments, and views were received from interested parties. The verbatim transcript of this hear-

ing, as well as the numerous comments, exhibits, and briefs submitted to OSHA before, during and after the hearing, are part of this rulemaking record, along with portions of the record in the earlier benzene proceeding which were relevant to the issues herein. The rulemaking record was originally scheduled to close on June 8, 1978, but, at the request of participants, was kept open until June 12, 1978.

These amendments are based on a careful consideration of the entire record of the informal rulemaking hearing, including the transcript, exhibits, and prehearing and post-hearing written comments. Copies of the official list of hearing exhibits, comments, and notices of intent to appear at the hearing can be obtained from the Docket Office, Docket H-059A, Room S6212, U.S. Department of Labor, 3rd Street and Constitution Avenue N.W., Washington, D.C. 20210.

III. Regulatory Analysis and Environmental Impact

Since an economic impact statement for the permanent standard (43 FR 5918) was prepared by OSHA pursuant to Executive Orders 11821 and 11949, OSHA has not performed a separate regulatory analysis pursuant to Executive Order 12044 (43 FR 12661, March 24, 1978). The economic analysis for the permanent standard considered the economic impact of compliance on employers with operations utilizing liquid mixtures containing any amount of benzene (43 FR 5934-5941). This amendment exempts from the permanent standard operations utilizing 0.5 percent or less benzene (0.1 percent or less after 3 years) and, therefore, reduces the cost of compliance with the standard.

In view of the fact that the amended standard does not require that employers reduce the amount of benzene in their products, costs involved in reducing the percentage of benzene in liquid mixtures in order to avoid coverage by this standard have not been attributed to the amended standard.

The final environmental impact statement published January 1978, prior to the issuance of the permanent benzene standard concluded that the standard would have a beneficial impact on the workplace environment and also that beneficial effects on the environment external to the workplace may also be anticipated. This amendment to the permanent benzene standard may result in employers switching to other solvents (containing lower benzene contamination levels). However, the atmospheric impact of such action is not expected to be significant. Where reformulation is accomplished to reduce organic solvent usage, the atmosphere will realize a reduction in total hydrocarbon load. As these types of actions were addressed in the final environmental impact statement, this amendment is not expected to alter the basic conclusions contained in that document. Accordingly, it was concluded that no new environmental impact statement was necessary for this amendment.

IV. Principal Issues Involved

The following is a discussion of the major issues involved in the rulemaking on the proposed percentage exclusion and an analysis of the evidence submitted into the record. The exhibit numbers refer to the certified exhibit list of docket H-059A. The first number designates the particular exhibit on that list. Where the exhibit contains more than one item, the second number references the particular item of the exhibit. The designation "tr." refers to the transcript of the hearing on percentage exclusion and indicates the pages of that transcript which are referenced. Furthermore, the designation "PC" refers to post hearing comments submitted by interested parties. All references are intended to provide examples of record support for the information stated.

(1) WHETHER WORK OPERATIONS SHOULD BE EXEMPT FROM § 1910.1028 WHERE THE SOLE OCCUPATIONAL EXPOSURE TO BENZENE IS FROM LIQUID MIXTURES CONTAINING LESS THAN A SPECIFIED PERCENTAGE OF BENZENE

The majority of those responding recommended that the benzene standard be amended to exclude from its coverage liquid mixtures containing less than a specified percentage of benzene. Reasons in support of this form of exemption varied. Some participants argued that exposure to low levels of benzene does not result in any health hazard, particularly leukemia (tr. 225, 391, 313, and exhibits 18-34, 63, 77, 84, 91). Other participants pointed out that they do not add benzene to their products but that benzene is an unavoidable contaminant in all petroleum based products (tr. 68, 78, 88, 106, 107, 120, 129, 132, 163, 168, 187, 215, and exhibits 18-41, 93, PC-5-8). Oil and gas producers stressed that benzene is a natural contaminant of crude oil and gas and that it is technologically infeasible to remove benzene at the wells (exhibits 18-77, 85, 1, 19). Refiners contended that it is economically prohibitive to remove benzene from their process streams, particularly within a short timeframe (exhibit 18-48). Most industry participants presented data indicating that the low levels of benzene in the liquid mixtures present in their workplaces produced airborne concentrations below the standard's permissible exposure limit of 1 ppm. (This data is discussed below under issue 6.)

Objections to any percentage exclusion for airborne exposure were raised by the Oil, Chemical & Atomic Workers (tr. 400). OCAW argued that, even where low percentages of benzene were present in liquid streams, refinery process units were subject to frequent leaks resulting in employee exposures above 1 ppm. OCAW contended that only where process units are well maintained, can exposures be reduced to the permissible exposure limit, but that such high quality maintenance cannot be guaranteed (tr. 402).

The United Rubber, Cork, Linoleum & Plastic Workers of America (URW) contended by way of comment that

while reduction of the amount of benzene in a liquid can result in reduction of airborne concentrations to conform with a PEL of 1 ppm, reduced levels cannot be attained in certain processes unless ventilation control is provided. URW also objected to permitting dermal contact with benzene mixtures where there has been no documentation of a "no-risk" health factor to benzene on skin contact, and recommended that temporary variances be sought by industry in situations where the use of protective clothing is a problem (exhibit 18-33).

The Public Citizen Health Research Group opposes the proposed amendment on the grounds that there is no safe level for exposure to a carcinogen and that liquid mixtures containing 0.1 percent benzene have been shown to give rise to exposure levels in excess of the PEL of 1 ppm (exhibit 18-94).

For different reasons, the American Petroleum Institute also urged that a percentage exclusion not be adopted, other than possibly for dermal exposure. API's objections to a percentage exclusion were based on the view that the medium or matrix in which benzene is found, the environmental conditions of temperature, humidity, air movement, and physical volume of space, the physical nature of the system in which benzene is found—namely whether in a closed or open system, and work practices are all critical to reduction of benzene exposure. In lieu of a percentage exclusion, API proposed that OSHA limit the scope of the benzene standard by adopting appropriate triggering mechanisms for activation of individual provisions of the standard. Thus, initial monitoring of airborne exposures should occur, in API's view, only when professionals, acting for the employer, have reason to believe that employee exposure is above the level which triggers the monitoring requirement (tr. 353).

Dr. Hervey B. Elkins testified on behalf of AISI that a percentage exemption would be appropriate inasmuch as naturally occurring benzene is found as a contaminant in many liquids employed in industry, formulation of many products will involve ingredients which often contain benzene in small quantities, and many products are made by chemical reactions employing benzene as a raw

material. Dr. Elkins indicated that to completely eliminate the last traces of benzene from these materials may be very difficult (PC 82).

(2) WHETHER 0.1 PERCENT BENZENE IS THE APPROPRIATE PERCENTAGE FOR EXEMPTION, OR WHETHER THE PERCENTAGE FIGURE SHOULD BE HIGHER OR LOWER

Some participants supporting a percentage exemption indicated that 0.1 percent would be of no significant benefit to them since the benzene contaminated mixtures they used contained benzene in excess of that figure. They also argued that a higher percentage exemption would be appropriate since the airborne concentrations arising from the higher benzene content mixtures did not generally exceed 1 ppm.

Further, industry participants provided evidence that, at present, many suppliers cannot furnish the various benzene-contaminated materials used in their processes with a benzene content as low as 0.1 percent. (This evidence is discussed in detail in issue 5.) For example, tire manufacturers testified that the rubber solvents used in tire building could not be obtained with any confidence that the benzene content would not be up to at least 0.7 percent. They maintained, therefore, that a percentage exemption of at least 0.7 percent would be appropriate, especially to provide relief from the requirement for protective clothing which is infeasible in these operations (tr. 68, 87, 108, 170, 188, 212, 215).

The Adhesives & Sealant Council (tr. 224), Wilhold Glues (tr. 224), St. Clair Rubber Co. (tr. 260), Miracle Adhesive Corp. (tr. 268), DuPont (tr. 313), the American Iron & Steel Institute (tr. 396), and others (exhibits 18-16, 21, 61, 53, 55, 56, 45, 108) suggested that, because of the unavailability of low benzene solvents and the lack of potential for exposure above 1 ppm, that a 1.0 percent exemption would be appropriate. The B. F. Goodrich Co. indicated that while they would be willing to comply with a 0.1 percent exemption as it would apply to generation of airborne concentrations, a special action level of 0.5

percent for activation of dermal protection requirements would be necessary for them to be able to comply with the standard. Other participants argued that 0.1 percent is inappropriate since exposures below 1 ppm occur in such operations as oil and gas production with crude oil and gas liquids containing up to 4 percent benzene (exhibit 18-71, PC 81).

Industry participants endorsing a 0.1 percent exclusion did so primarily because the benzene containing materials used in their operations generally contained less than 0.1 percent benzene and they would thus be exempt from the standard (exhibits 18-29, 37, 46, 70, 89, 106, 107).

Dr. Hervey Elkins testified that, while it may not be possible to establish liquid percentage limits that will guarantee, with complete certainty in every possible situation, airborne concentrations that will not exceed a specified level, it would be logical and appropriate to accept a particular percentage exemption which would most likely, based on calculations of available data, be consistent with a permissible exposure limit of 1 ppm. The calculations provided by Dr. Elkins were based on theoretical considerations, and on extrapolation from data in papers written by him. The mean of all values of benzene percentage limits in liquid mixtures consistent with a permissible exposure level of 1 ppm was calculated by Dr. Elkins to be 0.5 percent (PC 82).

(3) WHAT IS THE CURRENT PERCENTAGE (OR RANGE OF PERCENTAGES) OF BENZENE IN LIQUID PRODUCTS, SUCH AS PRINTING INKS, PETROLEUM SOLVENTS SUITABLE FOR TIRE BUILDING, ADHESIVES, SEALANTS, PAINTS, COATINGS, DETERGENTS, INSECTICIDES, DISINFECTANTS, WAXES, FLOOR FINISHES, CRUDE OIL, PETROLEUM SOLVENTS OF VARYING GRADES, GAS LIQUIDS, LUBRICATING OILS, PETROCHEMICALS, GASOLINE IN REFINERY STREAMS, AND SIMILAR PRODUCTS

Participants who furnished information on this issue generally indicated that, since benzene is primarily a contaminant rather than an intended final ingredient, the

benzene content of liquid products would vary not only from supplier to supplier but also from the same supplier. The American Petroleum Institute has indicated that production factors, which cause varying benzene content in their products, include differences in crude runs, the nature and efficiency of individual refinery process and the specific balance of final products produced at any point in time (PC 104).

Tire manufacturers reported rubber solvents used in tire building as containing up to 1.0 percent benzene, with only one supplier claiming capability of supplying solvents with 0.1 percent benzene or less. However, industry analysis of that company's shipments indicated benzene content from 0.097 to 0.137 percent (tr. 88, 95, exhibits 18-45). Petroleum based solvents used in the formulation of adhesives and glues was reported to vary from 0.3 percent to 3 percent (exhibits 18-26), while the finished products and other products such as paints, waxes, floor coatings, and printing inks, normally contain benzene well below 0.1 percent. The benzene content of gasoline was reported as covering a range from 0.5 to 3.5 percent with most samples containing less than 2.0 percent benzene (tr. 344). The American Petroleum Institute submitted results of analyses for benzene on 1,007 samples of crude oil, liquid condensate, natural gas liquids, and gas plant streams. A summary of this data reveals 49 percent of the samples containing less than 0.1 percent benzene, 34 percent containing between 0.1 and 0.5 percent benzene, 10 percent containing between 0.5 and 1.0 percent benzene, 5 percent containing between 1.0 and 2.0 percent benzene, and 2 percent of the samples containing greater than 2.0 percent benzene (PC 81). Rohm & Haas Co. reported that none of their 2,768 products, primarily synthesized organic chemicals, contained greater than 0.1 percent benzene and that benzene was an unintended contaminant in all but 2 of those products (exhibits 18-31).

(4) WHAT IS THE CURRENT PERCENTAGE (OR RANGE OF PERCENTAGES) OF BENZENE IN OTHER SOLVENTS COMMONLY USED AS SUBSTITUTES FOR BENZENE SUCH AS TOLUENE, XYLENE, HEXANE, AND SOLVENT NAPTHAS

Data provided on this issue came primarily from companies not using benzene as a raw material but using materials such as toluene and xylene and other solvents contaminated with benzene. It was indicated, however, by the rubber manufacturers and adhesives and sealant manufacturers, that reformulation or substitution of materials containing no benzene would be infeasible and could possibly diminish the integrity of the final product (tr. 101, 213, 254, 315).

The benzene levels reported in other solvents were somewhat varied, again due to different suppliers, process conditions and equipment used in their manufacture. As a result, it is difficult to identify specific percentages of benzene content in substitute substances with any degree of accuracy. For example, the Adhesives & Sealant Council, Inc., reported that members whose hexane suppliers are located on the west coast show benzene levels of 0.3 percent or higher, while members in other parts of the country purchase hexane with benzene content typically below 0.1 percent. Ranges of benzene impurity reported by the Council include hexane 0.001-2.3 percent; toluene 0.005-0.24 percent; rubber solvent up to 1.0 percent; naptha 0.1-1.0 percent; and mineral spirits up to 1.0 percent (exhibits 18-45). The National Association of Printing Ink Manufacturers, Inc., indicated the following range of benzene content: heptane 0.1 percent-0.75 percent; heptane ("aromatic free") 0.01-0.02 percent; toluene 0.02-0.1 percent; lactol spirits 0.02-0.1 percent; xylene 0.15 percent; and aliphatic hydrocarbon blend 0.01 percent to 0.02 percent (exhibits 18-83). Other participants reported benzene at or below the 0.1 percent level in toluene, xylene, hexane and solvent napthas (exhibits 18-15, 28, 35, 38, 39, 46, 47, 58, 69, 88) while others reported levels in excess of 0.1 percent (exhibits 18-35, 39, 61, 70, 84,

90) with one report of the benzene content of toluene to be 15 percent (exhibits 18-61).

(5) TO WHAT LEVELS CAN THE PERCENTAGE OF BENZENE BE FEASIBLY REDUCED

Those participants, such as the rubber manufacturers and the adhesives and sealant manufacturers, who obtain their solvents from other sources, could not provide any detailed feasibility assessment since they did not have knowledge of the technological potential of their suppliers to reduce the percentages further than present levels. Further complications involved the refusal of solvent suppliers to guarantee a specific benzene level and the fluctuating benzene content found in a given solvent from supplier to supplier. Some suppliers appear reluctant to certify particular solvents since they have not designed their processes with benzene content specification as a consideration. The Manufacturing & Chemists Association testified that a feasibility assessment can be made only after their determination of the benzene content of streams and products is complete (tr. 286). Solvent purchasers generally indicated that, if the solvent industry is capable of reducing the percentage of benzene over some period of time, they would support a graduated exemption setting lower acceptable levels in the future to coincide with the technological ability of the solvent industry to deliver those percentages in dependable volume shipments sufficient to maintain production and employment (exhibit 18-41, 80).

The only specific projection relative to benzene content reduction was in terms of costs. Texaco estimated that benzene reduction in their refinery streams from present levels to 1.0 percent would cost $85 million, a reduction to 0.5 percent would cost $508 million, and a reduction to 0.2 percent would cost $1,381 million. Detailed analysis of how these figures were arrrived at however, was not made available (exhibit 18-48). Another study, which addressed the economic impact of reducing benzene content, is the Arthur D. Little study on gasoline, prepared for EPA in February of 1978 (exhibit 12b).

(6) WHAT AIRBORNE CONCENTRATIONS OF BENZENE RESULT FROM THE PERCENTAGE OF BENZENE IN EACH PRODUCT

Comments and testimony presented on this issue generally revealed that in the industrial setting the benzene content of the liquid mixture plays only a part in the resultant airborne concentration to which employees may be exposed. The evidence regarding the other factors affecting airborne concentration are discussed under issue 7.

Monitoring data submitted to the record has provided a reasonable description of expected exposure levels in the various industrial segments affected by the proposed amendment. As previously discussed, Dr. Hervey Elkins submitted calculations indicating that a 0.5 percent benzene content in liquid mixtures would appropriately be consistent with a 1 ppm permissible exposure limit. The monitoring data submitted tends, for most all cases, to support Dr. Elkins' calculations. For example, General Tire & Rubber Co. submitted data for tire building operations which indicated resultant benzene exposures from rubber solvents containing greater than 0.5 percent benzene did exceed 1 ppm, while solvents with benzene content below 0.5 percent did not (exhibit 18-41). Exposures reported by B. F. Goodrich resulting from up to 0.3 percent benzene content indicate that the companion air levels of benzene were below 0.5 ppm in 95 percent of the cases and only one out of 255 samples was as high as 1.1 ppm (exhibit 18-75). While the Goodyear data tended to suport the proposition that exposure levels, in practice, will generally not exceed 1 ppm with low benzene content liquid mixtures, Goodyear's data from one tire manufacturing plant using from 0.263 to 0.280 percent benzene content rubber solvents indicated exposures between 1.11 and 1.98 ppm. Goodyear attributed these exposure levels to inadequate ventilation since other monitoring data they submitted from other tire building plants using up to 0.4 percent benzene rubber solvents showed exposure levels not in excess of 0.4 ppm. The adhesive and sealant manufacturers reported that, with liquid mixtures containing

up to 1.0 percent benzene, exposure levels never exceeded 1 ppm (exhibit 18-45). Printing ink manufacturers submitted data indicating that, while solvents used contained in some cases in excess of 0.1 percent benzene, exposure levels never exceeded 0.3 ppm (exhibit 18-83). DuPont provided results of tests from paint spraying operations showing that the use of liquid mixtures of 1 percent benzene will not result in airborne concentrations of benzene greater than 5 ppm, in most cases less than 0.5 ppm. Tests were performed with DuPont topcoat paints with 0.05 percent, 0.1 percent, and 1.0 percent benzene added. Benzene was intentionally added to the paints in an attempt to correlate benzene levels in the liquids with airborne benzene concentrations. The highest benzene level obtained was 4.3 ppm with a 1.0 percent benzene spike. Averaged over an 8-hour day, DuPont estimates that normal spraying operations with nonspiked paint will result in employee exposures below 1 ppm. Other DuPont data involving handling of 0.2 to 4.3 percent benzene in gasoline and 0.19 to 0.45 percent benzene in a p-xylene process stream resulted in time-weighted averages up to 0.38 ppm and 0.15 ppm respectively (exhibit 18-39).

Edison Electric Institute reported than exposures resulting from handling fuel oils containing 0.003 to 0.005 percent benzene resulted in exposures less than 0.2 ppm (exhibit 18-56). Husky Oil Co. reported refinery streams with 0.71 percent benzene and finished gasoline with 0.35 percent benzene as producing exposures of less than 0.11 ppm and 0.042 ppm respectively (exhibit 18-64). Earlier data submitted by NIOSH indicated that fuel oil containing less than 0.1 percent benzene gave rise to benzene concentrations of 60 ppm under conditions of elevated temperature, confined space and possibly inadequate ventilation. NIOSH indicated, however, that the sampling was done with detector tubes which are relatively inaccurate and subject to numerous interferences. (tr. 753-755, July 25, 1977, hearing)

While other participants (exhibits 18-24, 35, 49, 84, 87) supported the proposition that benzene levels in liquid mixtures greater than 0.1 percent would still not generally produce exposures to benzene above 1 ppm, some

participants provided data to the contrary. The United Rubber, Cork Linoleum & Plastic Workers of America (URW) (exhibit 18-33) referenced testimony presented by Dr. Robert T. Harris, of the University of North Carolina at the public hearing on the proposed benzene standard (docket H-059), in which Dr. Harris stated that bulk solvent percentages of benzene from 0.5 to 1.07 percent can produce exposure levels below and above 1 ppm, some as high as 12 ppm. The reliability of the results of this study were questioned by Dr. Curtis Smith of the Manufacturing Chemists Association who indicated that the findings as to the presence of benzene in the ambient air could have been artificially high because of interference of ketones which are present in the ambient air around rubber plants (tr. 299). URW submitted other exposure data from an Armstrong tire manufacturing facility (the "Harvard study") also indicating exposure levels above 1 ppm with solvents containing low levels of benzene. A number of participants, including Armstrong, questioned the reliability of the Harvard study (PC 89, 90, 91, 92, 105). Armstrong commented on the study as follows:

> The report itself makes it clear that no analyses were made by the Harvard study during the week of January 9, 1978, with respect to the bulk samples. Reference is made to the analysis by the Armstrong laboratory in June 1977 that benzene in Texol at that time was less than 0.1 volume percent. More than 6 months elapsed between such sampling of the solvent and the air sampling. It is to be regretted that in the only monitoring done to date with respect to an Armstrong facility, and a very limited sampling at that, the monitoring was not accompanied by an analysis of the solvent in use at the time of such monitoring.
>
> In addition, the sample period did not cover the full 8-hour period for computation of the time weighted average (TWA). The TWA, in fact, was estimated from a sampling time of approximately 2 to 3 hours.

> NIOSH in its Occupational Exposure Sampling Strategy Manual, DHEW (NIOSH) Publication No. 77-173 (January 1977) is critical of partial period sampling. The Manual states, at page 40, that the "sampled portion of the period should cover at least 70 percent to 80 percent of the full period." Indeed, in discussing the validity of a 6-hour TWA exposure average as compared with an 8-hour TWA standard, the Manual states, at page 41, that "[t]his type of measurement should be avoided if possible." It therefore follows that a significantly shorter period is even less valid (PC-91).

Other participants, sharing reservations relative to a particular percent exemption, did so on the grounds that exposure measurements from liquid mixtures containing 0.1 percent or less benzene did or could theoretically produce airborne concentrations of benzene in excess of 1 ppm or that variables such as ventilation, liquid temperature, work practices, etc. affected resultant benzene airborne concentrations to too great an extent to confidently rely on only benzene content for limitation of employee exposures (exhibits 18-32, 61, 72, 79, 92, 94, PC-S-8).

(7) TO WHAT EXTENT DO VARIOUS FACTORS, SUCH AS TEMPERATURE, DILUTION WITH AMBIENT AIR, WORK FACTORS, NATURE OF OPERATIONS, ETC., AFFECT THE RELATIONSHIP BETWEEN THE PERCENTAGES OF BENZENE IN THE VARIOUS PRODUCTS AND RESULTING AIRBORNE CONCENTRATIONS, AND SHOULD ANY EXEMPTION BE LIMITED TO THE USE OF THESE PRODUCTS UNDER PARTICULAR CIRCUMSTANCES

As previously indicated, most participants agreed that factors other than benzene content can play a significant role in resultant airborne concentrations of benzene. Goodyear stated that ventilation, climate, work habits, etc., would definitely affect the airborne concentration of benzene, and submitted monitoring data from an older tire manufacturing facility and two newer plants for

comparison. The two newer facilities using rubber solvent containing 0.4 percent and 0.2 to 0.3 percent benzene experienced airborne concentrations of benzene at 0.45 and 0.25 ppm respectively. The older tire plant using rubber solvent with 0.263-0.280 percent benzene experienced airborne concentrations of 1.11 to 1.98 ppm. Goodyear attributed this discrepancy to inadequate ventilation in the older tire manufacturing facility. Goodyear further indicated that, while they could not determine an exact correlation from their data, variables other than benzene content could cause up to an 80 percent variance in resulting airborne concentrations. (PCS-8). Other participants provided either theoretical or actual data indicating exposures greater than 1 ppm from low benzene content mixtures used under conditions of confined space, inadequate ventilation, elevated temperatures etc. (exhibit 18-32, 92). URW submitted previous testimony of Dr. Robert T. Harris presented at the public hearing on the proposed benzene standard (docket H-059) in which Dr. Harris stated that "* * * the lower the benzene content of the solvent, the lower the potential for exposure, but a low benzene content of solvent alone does not assure that a particular air concentration will not be exceeded" (exhibit 18-33).

As mentioned previously, Dr. Hervey Elkins submitted calculations estimating that a 0.5 percent benzene content would not normally be expected to produce airborne concentrations of benzene greater than 1 ppm. Dr. Elkins addressed the affect of other factors on his calculations:

> It is self-evident that the factors mentioned (temperature, ventilation, work practices, nature of operations) will affect the relationship between the percentage of benzene in a liquid product and the resulting concentration of benzene vapor in the air. Important factors not mentioned include the quantity of substance consumed or processed, the area of the liquid surface which is exposed to the air, and the vicosity of the liquid.
>
> The exemption percentages proposed (i.e., 0.5 percent to meet 1 ppm) were based on rather severe

conditions: complete or free evaporation of the benzene and other volatile ingredients, limited only by the provision that the permissible limits of the vapors of the other components of the liquid must not be exceeded.

With some high boiling liquids, such as heavy oils and tars, there is little evaporation of the base material, even when heated to temperatures well above the boiling point of benzene. In theory, processes employing such materials at elevated temperatures and with large surface areas exposed (as might occur in certain coating or impregnating processes) could produce concentrations of benzene vapor in the surrounding air in excess of the postulated permissible exposure levels, even when the concentration of benzene in the liquid is less than the limits recommended above.

On the other hand, handling and processing such liquids in enclosed or partially enclosed spaces, with limited exposure of liquid surfaces to air, and at temperature such that the material is not highly fluid, would result in benzene concentrations well below the postulated permissible exposure levels, even when the percentage of benzene in the liquid is in excess of the limits recommended above.

For the sake of simplicity, it is recommended that * * * the 0.5-percent exemption percentage be applied if the airborne permissible exposure limit is 1 ppm—with the proviso that if operations involving heating of the liquids and exposure of large surface areas are carried out, at least a one time monitoring of the area of benzene in air be done, if the benzene content of the liquid exceeds 0.1 percent. (PC-82)

API argued in its post-hearing brief that the record evidence does not identify a specific percentage of benzene which will guarantee that a given PEL will not be exceeded under all work environments and that, therefore, any percentage exemption must also take account of the roles of many other controlling factors. API further stated that, regardless of the benzene content in their streams, the nature of their oil and gas operations is the most important factor in considering potential exposures and need for regulation of their segment of the industry. API witness Dr. William G. Domask testified that:

> It is evident from the data and information presented here that well-maintained, closed-system operations in general represent a low risk for exposure to benzene.
>
> Specifically, petroleum production, pipeline, and marketing personnel air monitoring data reflect a very low risk of exposure to benzene vapor at all concentration levels of benzene in the liquids handled by these segments of the industry.
>
> Similarly, data for the closed-system portions of refining operations indicate a very low level of exposure to benzene (PC-81).

While many other participants addressed this issue and acknowledged the significance of factors other than benzene content relative to resultant airborne concentrations of benzene, there were no recommendations relative to a practical translation of requirements for a homogeneous regulatory conclusion which would give full weight to those factors.

(8) TO WHAT EXTENT, AND FOR WHICH LIQUID MIXTURES, ARE BENZENE-FREE SUBSTITUTES AVAILABLE

Most industry participants argued that benzene-free substitutes are not commercially available, are not suitable for their process due to incompatibility with other materials and existing air pollution control systems and methods, are economically prohibitive, or would reduce product performance (exhibit 18-15, 21, 39, 41, 54, 80, 90, 109). The Public Citizen Health Research Group argued that benzene substitutes are available (exhibit 18-94).

However, the record indicates that "benzene-free" substitutes are not generally available for the majority of industrial uses.

(9) IF LIQUID MIXTURES OF SPECIFIED PERCENTAGES ARE EXEMPT FROM THE OTHER PROVISIONS OF THE BENZENE STANDARD, SHOULD THEY NEVERTHELESS BE SUBJECT TO THE LABELLING REQUIREMENTS OF THE STANDARD. CONVERSELY, IF SUCH MIXTURES ARE NOT EXEMPT FROM THIS STANDARD, SHOULD THEY BE EXEMPT FROM THE LABELLING REQUIREMENTS

Industry participants indicated that some relief from the labeling requirements was necessary. They argued that, without some labeling exemption, liquids which contain trace amounts of benzene would require cancer hazard labels. They objected to such labeling on the following grounds: lack of associated health hazard requiring warning; economic burdens; uncontrolled use of warning labels dilutes effectiveness of warning messages; and, the ubiquitous nature of benzene in petroleum distillates. The recommendation of industry participants was that any liquid mixture exemption of a specified percentage should include an exemption from the labeling requirements (exhibit 18-21, 29, 31, 37, 41, 42, 69, 71, 72, 79, 83).

DuPont testified that, without a labeling exemption to allow additional time to clear existing inventories carrying levels of 0.1 to 1.0 percent benzene, the cost of locating already packaged containers and labeling them would run to about $31 million (tr. 317). DeSoto, a manufacturer of paints, industrial coatings, detergents, furniture and fireplace accessories, estimated their cost of labeling present inventory at $700,000 (exhibit 18-43). Another paint and coatings manufacturer, Pratt & Lambert, Inc., estimated a current inventory of 1.4 million containers, which without an exemption, would cost $700,000 to label (18-44).

(10) OTHER RELATED ISSUES

(a) *Monitoring feasibility.* A number of industry participants provided data indicating potential difficulties in obtaining industrial hygiene and analytical services. The cost burden and reported lack of monitoring service capabilities in some locations which would result if some exemption were not provided to part of the industry, would render compliance with parts of benzene standard impossible (exhibit 18-1, 3, 9, 12, 20, 37, 39, 65, 68, 82, 87).

The Manufacturing Chemists Association stated that analysis for benzene requires equipment which is expensive and which must be operated by specialists. They maintained that, due to interference from other substances, multiple gas chromatography analyses on a single product or use of mass spectrometric equipment together with gas chromatography, available only in large laboratories, are required to produce good analytical results (PC-103). NIOSH addressed the problem of interferences in a post-hearing submission (PC-88) in which they report that work by Levadie and MacAskill, "Analytical Chemistry," 48, 76, 1976, and by Esposito and Jacobs, "American Industrial Hygiene Journal," 38, No. 8, 401, 1977, describes the modifications to the NIOSH sampling and analytical methods for benzene, S311, necessary to solve the problem of interferences arising from ketone materials in the analysis for benzene. NIOSH also noted that the price of mass spectrometer systems has declined steadily over the last five years. It is NIOSH's position, therefore, that benzene can be identified with confidence using the NIOSH recommended method, that interferences can be handled by simple extraction techniques prior to gas chromatography, that detectors or columns are readily available and within the normal financial limitations of most commercial laboratories, and that recourse to mass spectrometry is unnecessary.

(b) *Miscellaneous comments.* Due to the unique nature of the motor carrier industry whose employee exposure to benzene is occasional and then only minimal, the National Tank Truck Carriers, Inc. recommended that if OSHA has any concern over motor carrier's employee exposure to benzene, OSHA should petition the Department of Transportation to develop regulations, thus avoiding regulatory imposition by another agency over an already regulated sector (tr. 414).

The National Agricultural Chemicals Association argued that OSHA has no authority to require labeling of

pesticide products and no need to duplicate or interfere with the labeling controls imposed by the Environmental Protection Agency (exhibit 18-53).

The National Retail Merchants Association urged an exemption from the standard for retail stores since employee exposure in those stores is from consumer goods which are in closed containers. They also argued that, while paint cans are opened for mixing and coloring, the brief and intermittent nature of the operation would not result in sufficient benzene exposures to merit regulation. NRMA further stated that the standard should not apply to existing inventories since retailers would then be unable to sell products they already owned (exhibit 18-37).

V. Analysis and Feasibility

OSHA has concluded that it is appropriate to amend the permanent benzene standard to provide for a percentage exclusion. Specifically the agency has exempted from all the provisions of the standard for the first 3 years following the effective date of this amendment, liquid mixtures containing 0.5 percent or less benzene, and thereafter liquid mixtures containing 0.1 percent or less benzene. Further, OSHA has exempted from the labelling requirements liquid mixtures containing less than 5.0 percent benzene which are already packaged.

OSHA recognizes that the scope of the permanent benzene standard (29 CFR 1910.1028), unamended, is so broad as to encompass work place operations utilizing liquid mixtures with any amount of benzene however small (tr. 30). OSHA's view that there is no level of benzene exposure that is without some attendant health risk remains unchanged. However, because of the ubiquitous nature of benzene, i.e., its presence in a myriad number and type of worksites (benzene is a contaminant in most, if not all petroleum-based liquid mixtures), OSHA believes that it is proper to focus industrial hygiene and medical resources on those operations with higher exposures and which present the greatest potential risk to worker health. This decision is in accord with the evidence developed during the recent rulemaking which

revealed the need to and appropriateness of limiting the scope of the standard.

The mechanism chosen to effectuate this relief must in OSHA's view be consistent with the intent of the permanent standard, which is to minimize the risk to worker health to the greatest extent feasible. The framework within which the agency has examined this issue was articulated by the Director of OSHA's health standards programs, Grover C. Wrenn, at the outset of the informal hearing:

> Since the standard itself establishes a permissible exposure limit for benzene, we would certainly endeavor to set an exemption which assured that employees exposed to materials exempt from coverage under the regulation are subject to no greater exposure than employees who are subject to the provisions and protection of the standard (tr. 16).
>
> And one of the questions that was raised in the earlier rulemaking and one of the questions that is raised here is the question of the likelihood that exempting any particular category of materials from regulation, under the benzene standard—the likelihood that that exemption would provide a basis for being confident that workers involved with those exempt materials would not be exposed in a manner that was intended to be avoided by the benzene regulation (tr. 16).

The agency has considered and reviewed several approaches for limiting the scope of the permanent benzene standard suggested by participants to the rulemaking. These options included a single percentage exclusion applicable to all provisions of the standard, as was set forth in OSHA's proposed amendment in the Federal Register notices of March 28, 1978 (43 FR 12890) and April 28, 1978 (43 FR 18215). Such an approach was recommended by many participants as cited under the discussion of issue 1. Another option called for a general percentage exclusion, but with different levels for certain provisions of the permanent standard. This type of amendment, which was suggested by the Rubber Manu-

facturers Association and member companies (Exh. 92), specifically called for a higher percentage exclusion for the dermal and labelling provisions of the standard relative to other sections. A third option was that relief from the standard by based not on a percentage exclusion (with perhaps the exception of the dermal provision) but rather be based upon actual employee exposure levels. This recommendation was made by API, NPRA and member companies and also supported by OCAW (Ech. 104, Tr. 400). A final option would include a general percentage exclusion with the additional proviso that, in the case of severe or unusual work situations, the permissible airborne limits should not be exceeded as determined by monitoring. (Exh 27-C.1, PC-82)

OSHA has carefully evaluated these and other possible approaches and, based upon a review of the evidence and views contained in the rulemaking proceedings, has concluded that a percentage exclusion amendment applicable to all provisions of the standard most adequately satisfies, for regulatory purposes, the dual intention of appropriately limiting the scope of the permanent benzene standard while not exposing exempted employees to greater exposures than employees covered by the standard.

The record evidence of percentage exclusion rulemaking establishes, as shown in the preceding discussion of issues, that a variety of liquid mixtures with small or "trace" amounts of benzene generally result in exposure levels below the permissible exposure limit of the permanent benzene standard in a wide variety of industries. OSHA has determined, by examining the relationship of the percentages of benzene to resultant exposure levels, that generally an appropriate percentage exclusion can assure that employees who would be exempt from the coverage of the benzene standard are not exposed above the level set in the standard (tr. 16). Furthermore, it is OSHA's view that a percentage exclusion will encourage employers to act to reduce the amount of benzene present in liquid mixtures utilized in their workplaces or present in their products and, therefore, reduce the potential health hazard to employees. The record clearly establishes that, since publication of the permanent benzene stand-

ard, paint manufacturers and other solvent users have already examined the need for benzene in their liquid mixtures, and have made extensive efforts to obtain solvents with lower percentages of benzene. OSHA believes that an appropriate percentage exclusion will be an incentive to many other employers to reduce benzene levels and thus minimize the leukemia and other health risks to their employees.

In arriving at the conclusion that an "across-the-board" percentage exclusion is the appropriate means to afford an opportunity for relief from the standard without subjecting workers to undue risk, OSHA recognizes that factors other than the benzene content of liquid mixtures can act to significantly modify the resulting levels of airborne exposure. Variables such as the nature of work operations and work practices, and quantifiable parameters such as temperature, size of evaporative area, and especially ventilation all have been shown to play an important role. This data thus supports Dr. Harris's earlier conclusions that there is no necessary correlation between the amount of benzene in liquid mixtures and resulting airborne levels. However, defining the parameters and determining the exact combination of factors which significantly increase exposure, a necessary accomplishment for regulation on this basis, is not possible and no witness could suggest means of doing so. Moreover, the preponderance of evidence submitted to this rulemaking (most of which was not available at the earlier rulemaking) manifestly establishes, based on objective sampling data derived from current industrial settings, that for the vast majority of worksites, small amounts of benzene in liquid mixtures do not result in worker exposures above 1 ppm.

An additional reason for not adopting alternative strategies to amend the permanent standard is that the record did not provide evidence for the need to provide different exemption levels for different provisions. Manufacturers of rubber goods argued that an "action-level" concept be applied to the dermal section of the standard because of the infeasibility of performing certain manual operations in their industry without some skin contact

with benzene-containing solvents. However, as was explained in the preamble to the permanent standard, from the point of view of choosing a "safe" level, the permissible exposure limit should be zero (exhibit 3A). In the case of airborne exposure, clearly this was not attainable and their airborne permissible exposure limits established were not "no-effect" levels, rather were based on feasibility considerations. However, with respect to dermal contact, avoidance of skin exposure is feasible for workers in most industrial sectors simply by the use of suitable protective clothing, such as impermeable gloves. OSHA recognizes that in tire-building, the record evidence shows that at present there are no suitable methods available to prevent skin contact with solvents containing a small amount of benzene. However, the record evidence establishes that rubber solvents with 0.5 percent benzene, which are suitable for use in tire operations, are already available in sufficient quantities. Accordingly, the exemption of 0.5 percent liquid mixtures from all the provisions of the benzene standard, will substantially relieve the feasibility problems in tire building operations. Furthermore, the 3 year stepdown provision of the amendment from 0.5 to 0.1 percent exclusion levels will allow time for increased production of solvents containing lower amounts of benzene and for development and evaluation of alternative methods of compliance with the standard's dermal provision.

Some participants suggested that a higher exemption level apply to labeling (Tr. 68, 188). OSHA does not agree. The labeling requirement of the permanent standard serves to inform the worker of the hazard associated with working with benzene containing liquid mixtures. Use of a higher percentage exemption for this provision could result in the employee not being apprised of the danger in situations where exposure might be excessive.

API has argued that an "across the board" percentage exclusion is not an effective method by which to amend the standard, and that, in general, an exemption predicated on exposure levels is a better way of dealing with the problem presented by liquid mixtures containing small quantities of benzene (PC 104). While acknowledging

that there are other factors in addition to benzene concentration which may significantly affect airborne exposure levels, OSHA believes that there is sufficient record evidence which demonstrates that with low levels of benzene contamination airborne exposures are generally below the PEL and frequently below the action level. Many participants in the rulemaking also supported this conclusion. Furthermore, API's recommendation that various provisions of the permanent standard be triggered by workers' exposure levels is, to a great degree, already incorporated into the standard by OSHA's use of the action level concept. The objective of the benzene standard is to provide necessary protection to employees from the hazards of benzene exposure, and to this end, the standard imposes upon employers different compliance requirements depending on the level of employee exposure, with minimal requirements imposed where employee exposure is below the action level.

The primary difference between API's suggested use of an "exposure determination" and OSHA's decision reflected in the standard is that API would not require initial monitoring in all cases but rather would rely upon professional judgment to determine whether various provisions of the standard apply. However, it should be noted that API's judgment as to which operations in the petroleum industry have low exposures is based upon objective sampling data submitted to this record; to the extent that such data exists the initial monitoring requirements of the permanent standard may be satisfied.

OSHA recognizes that conditions, such as elevated temperatures, inadequate ventilation, confined space, quantity of material used etc., could in some cases act to produce exposures above the PEL even if the same benzene percentages would in other operations result in exposures less than the PEL. However, as already stated, the record does not provide a sufficient basis upon which to identify and define these variables for regulatory purposes.

The results of monitoring of employee exposure submitted by numerous participants demonstrates that, by and large, the use or presence of liquid mixtures contain-

ing benzene with maximum concentrations of 0.5 percent benzene results in airborne concentrations of less than 1 ppm and frequently less than the action level of 0.5 ppm. However, the low airborne concentrations reported are not necessarily due to the inherent nature of the liquid mixtures utilized (exhibit 18-32), but rather are in part the result of the maintenance and effectiveness of engineering controls to limit exposures. Therefore, maintenance of these low exposure levels can be dependent upon the continued use of engineering controls. This is illustrated by the testimony of Goodyear which shows that, in contrast to the majority of their operations, which indicated that use of solvents containing up to 0.4 percent did not result in exposure levels greater than 0.4 ppm, in one plant with inadequate ventilation, exposures greater than 1 ppm were observed when the solvent utilized contained only 0.26 to 0.28 percent benzene. (PC-S-8). In the case of refineries, although the benzene content of liquid streams may range up to 3.5 percent by volume or higher, the great majority of worker exposures are less than 0.5 ppm (tr. 339-345.) It is evident that such low exposures in the petroleum industry are due to the outdoor setting and, importantly, to the use of closed systems. Although not always explicitly stated, the low exposures measured in some situations, such as the use of benzene-containing solvents by rubber manufacturers, appears to be the result of engineering controls as well as effective work practices.

Close examination of Dr. Elkins' calculations also indicates that a percentage exclusion level of 0.5 percent may not be sufficiently conservative. His calculated average of all values of benzene percentage limits, which was consistent with exposures of 10 ppm (the time-weighted average PEL of the previous standard) was approximately 1 percent when utilizing a total upper limit concentration of 500 ppm for petroleum distillates (PC-82). If the same underlying assumption is used (rather than utilizing NIOSH's recommended 350 milligrams per cubic meter which is not presently in effect) to calculate the percentage of benzene in a liquid mixture consistent with the 1 ppm PEL of the permanent standard, the mean value

would decline approximately 10-fold or to a level of about 0.1 percent benzene in liquid mixtures (tr. 393-94). Elkins' data takes into account abnormal worst case work situations. Therefore, a 0.1 percent exclusion level should maintain workplace levels at below the permissible exposure limit even in the abnormal work situations cited by Dr. Elkins.

In adopting an across the board exclusion level, two problems arise: (1) In some cases, where the benzene stream content is in excess of the prescribed percentage and the standard there applies, exposures may well be below the PEL or action level; and (2) in certain cases, the exemption of work operations where the benzene content of liquids are below the prescribed exclusion level may produce exposures in excess of the PEL.

In the first case, although exposures may be low, the potential exists for excessive exposures, such as in the case of leaks, spills and process upsets from enclosed systems. The agency believes, that because of this potential, the requirements of the permanent standard are necessary for the protection of employees working in such areas. In the second situation, this agency recognizes that adoption of a 0.1 percent exclusion level does not, in all cases, assure that resulting airborne exposures will necessarily not exceed the action level of 0.5 ppm or even the permissible exposure limit of 1 ppm. OSHA further recognize that 0.5 percent factors other than the percentage of benzene may become more significant in determining exposure levels. However, the record does not indicate that exposures greater than 1 ppm have been demonstrated to be commonly found in existing industrial situations where benzene levels in liquid mixtures are less than 0.1 percent.

Ideally, the percentage exclusion level chosen should be so low as to assure that in all instances, the PEL will not be exceeded. Participants representing users of benzene-containing solvent mixtures who recommended exemption levels of 0.5 to 1 percent, conceded that they would readily utilize solvents containing even less benzene if they were available. While some participants from industry testified that they were able to obtain solvents with less than

0.1 percent on a regular basis, the record evidence demonstrates that for most industrial processes liquid mixtures containing 0.1 percent or less benzene are not commercially available at this time. Thus, the percentage exemption level chosen by OSHA for amendment purposes must take into account the feasibility of supplying large volumes of liquids containing less than a specific amount of benezene to a multitude of industrial users.

Testimony from the producers of liquid mixtures which contain varying amounts of benzene indicate that the benzene which is present is there only as a contaminant and generally is not intentionally added to produce a particular property in the formulations or products. Furthermore, while it appears to be impossible to exclude very small amounts of benzene in many of these products MCA witnesses observed that the technology currently exists to produce liquid mixtures containing 0.1 percent or less of benzene (tr. 278). However, their testimony also demonstrated that reduction of benzene content to the 0.1 percent level is not a simple undertaking. Because benzene is a widespread contaminant in most petroleum-based liquid products, some time will be required to complete testing to determine the current levels of benzene in their products. Once this process is complete, industry will require an additional period of time to implement appropriate process changes which would assure low level benzene content. This latter phase is in some instances complex, as the percent of benzene is dependent upon existing production factors, such as differences in crude runs, the nature and efficiency of individual refinery processes and the specific balance of final products produced at a given point in time. In addition, it appears that market conditions may also be a significant factor determining the degree to which benzene has been extracted from petroleum-based streams. The record also indicates that only in the recent past have producers of benzene-containing liquids given significant consideration to the benzene content of their products (tr. 286).

Two studies addressed the economic feasibility of reducing benzene content in certain liquid mixtures (exhibit 18-48; exhibit 12B). However, it is OSHA's view that the

cost of reducing benzene content are not attributable to this percentage exclusion amendment. Reducing the benzene content in liquid mixtures in order to avoid coverage by the benzene standard is an option which the employer may exercise; it is not a requirement of the benzene standard that he do so. Employers may prefer to comply with the permanent standard, particularly where their employees are exposed below the action level, in which case the employer would need only to conduct initial measurement, record that measurement and train his employees. Since the standard does not compel reduction of benzene content, it is OSHA's view that costs involved in reducing the percentage of benzene in a liquid are not a consideration in this amendment.

Other than indicating that considerable time would be required to complete analysis of benzene content of their products, (exhibit 18-87) industry did not provide estimates nor specific recommendations as to the time frames required to effect production changes in order to produce liquid mixtures containing 0.1 percent of less of benzene in sufficient quantity to meet the anticipated needs of downstream users. Because of the above considerations, industry participants felt that OSHA should not at this time adopt a percentage exclusion at the level of 0.1 percent as proposed by the agency. However, it should be noted that the proposed permanent regulation, which did indicate that the agency was considering a 0.1 percent exclusion level, was published over a year prior to the most recent rulemaking. Review of the evidence submitted indicates that while not commercially available on a sufficiently large basis, mixtures with 0.1 percent or less benzene content have been produced and are available on a limited basis and are compatible with most processes requiring such mixtures.

The record evidence further demonstrates that mixtures with a benzene content of up to 0.5 percent are presently available in sufficient quantity to satisfy the needs of affected industrial segments and that suppliers of these liquid mixtures are attempting to reduce the benzene content still further. OSHA has, therefore, concluded that

0.1 percent benzene content can be feasibly attained on a commercial basis at some point in the future.

It is the judgment of the Agency that a period of 3 years is a sufficient and reasonable allowance for development and implementation of means and methods necessary for production of adequate supplies of 0.1 percent benzene content mixtures. Along with the consideration of feasibility, the record evidence indicating a relative lack of suitable "benzene-free" substitutes, dictates the need for providing a period for implementation which would meet the anticipated demand for solvents containing low percentages of benzene. In addition, the 3-year period before the stepdown to the 0.1 percent level, will allow those users of benzene-containing liquid mixtures to test for product integrity before commencing reformulation on a large-scale basis.

By adoption of the 0.5 percent exclusion level initially, many employers engaged in crude oil and gas production activities will be provided relief from all provisions of the permanent standard. The agency is aware that, by decreasing the exclusion level to 0.1 percent after 3 years, many of the facilities and employees in the petroleum production sector will then be covered by the standard. It is also recognized that since benzene is a naturally-occurring constituent of crude oil and natural gas, its level is not under the control of the employer. However, since compliance requirements of the permanent standard are directly related to the exposure level of the employees, and since it has been demonstrated that exposure levels of personnel in oil and gas production are generally below the action level of 0.5 ppm, the requirements of the permanent standard are minimal beyond the taking of an initial representative exposure measurement. The 3-year delay prior to the step-down to the 0.1 percent level also provides additional time for employers to obtain the required sampling information.

This amendment also exempts from the labeling requirement, liquid mixtures containing 5.0 percent or less benzene if the liquid mixture is already packaged on the effective date of this amendment. Record evidence indicates that there may be a large number of containers

already in the channels of commerce, particular consumer products, that would be subject to the labelling requirement if such an exemption were not provided. While the labelling of existing containers may be possible, it is also clear that it would require a substantial effort. Thus, imposition of the labelling requirement for liquid mixtures already packaged might well result in an excessive disruption of the commercial framework. For liquid mixtures packaged after the effective date of these amendments, the 0.5 percent exemption applies. Those employers who utilize or manufacture liquids containing 0.5 percent or less benzene will have 3 years to meet the labelling requirements, and may be exempt entirely if in that period of time they can reduce benzene concentrations below 0.1 percent.

OSHA has chosen a level of 5 percent or less benzene (by volume) contamination as the boundary for exempting liquid mixtures already packaged. Evidence developed during the rulemaking indicated that there may be some products already in the channels of commerce which may contain benzene well in excess of 1 percent and which may not have been analyzed and which would be difficult to track down. In addition, the 5 percent level chosen is similar to the requirement of the Consumer Product Safety Commission which, under the Federal Hazardous Substance Act Regulations (16 CFR 1500.14(a)(3)), mandates that products with 5 percent or more benzene receive a special label. In products with an average molecular weight similar to that of benzene, 5 percent by volume is similar to 5.0 percent by weight.

It is the agency's judgment that much of the National Tank Truck Carrier's Association's concerns regarding the imposition of the provisions of the permanent standard on their members will be substantially relieved as users of various liquid mixtures demand products containing less than the prescribed percentage levels of benzene. In the absence of the exercise of authority by the Department of Transportation in this matter, 1910.1028, as amended, applies to this industry (sec. 4(b)(1)).

EFFECTIVE DATE

This amendment is effective immediately on June 27, 1978. Since this amendment is a rule granting an exemption, the Administrative Procedure Act (5 U.S.C. 553) does not require a 30-day period before the amendment becomes effective. Section 533(d)(1) of the APA exempts rules which grant an exemption or relieve a restriction from the requirement that publication of a substantive rule be made not less than 30 days before its effective date. This amendment exempts from the permanent benzene standard operations utilizing liquid mixtures of 0.5 percent or less (0.1 percent or less after 3 years). Without this amendment, all employers with such operations would be required to implement the various protective requirements of the permanent standard, such as initial monitoring, training and recordkeeping. The amendment relieves them of this burden.

In addition the amendment exempts from the labelling requirements liquid mixtures which are already packaged in containers and which contain 5 percent or less benzene. Such containers would otherwise be subject to the labelling requirements of the standard. The amendment, therefore, relieves employers of the requirements to label these containers.

Accordingly, these amendments are effective June 27, 1978. As with the other operations exempted from § 1910.1028, the benzene standard contained in Table Z-2 of § 1910.1000 will continue to apply to the operations exempted by the amendments.

Upon the publication of this amendment, the limited administrative stay adopted by OSHA in conjunction with this rulemaking (43 FR 12891) is no longer in effect.

VII. AUTHORITY

This document was prepared under the direction of Eula Bingham, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue N.W., Washington, D.C. 20210.

Accordingly, pursuant to section 4(b)(2) and 6(b) of the Occupational Safety and Health Act of 1970 (84 Stat. 1592, 1593, 29 U.S.C. 653, 655), the specific statutes referred to in section 4(b)(2), Secretary of Labor's Order No. 8-76 (41 FR 25059), and 29 CFR Part 1911, Part 1910 of Title 29, Code of Federal Regulations, is hereby amended by adding new paragraphs (a)(2)(iii) and (k)(2)(iii) to 29 CFR 1910.1028.

Signed at Washington, D.C., this 21st day of June 1978.

EULA BINGHAM,
Assistant Secretary of Labor.

Part 1910 of Title 29 of the Code of Federal Regulations is hereby amended by adding a new paragraph (a)(2)(iii) and a new paragraph (k)(2)(iii) to § 1910.1028 to read as follows:

§ 1910.1028 Benzene.

(a) *Scope and application.* * * *

(2) This section does not apply to:

* * * *

(iii) Work operations where the only exposure to benzene is from liquid mixtures containing 0.5 percent (0.1 percent after June 27, 1981) or less of benzene by volume, or the vapors released from such liquids.

* * * *

(k) *Signs and labels.* * * *

(2) The employer shall assure that caution labels are affixed to all containers of benzene and of products containing any amount of benzene, except:

* * * *

(iii) Liquid mixtures containing 5.0 percent or less benzene by volume which were packaged before June 27, 1978.

(Secs. 4, 6, 84 Stat. 1593 (29 U.S.C. 653, 655); Secretary of Labor's Order 8-76 (41 FR 25059); 29 CFR Part 1911.)

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Nos. 78-911 & 78-1036

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1978

INDUSTRIAL UNION DEP'T, AFL-CIO,
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*,
Respondents,

and

RAY MARSHALL, SECRETARY OF LABOR,
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*,
Respondents.

On Petitions for a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

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JOINT MEMORANDUM IN OPPOSITION FOR RESPONDENTS THE AMERICAN PETROLEUM INSTITUTE, ET AL., THE RUBBER MANUFACTURERS ASSOCIATION, ET AL., THE CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION, E. I. DU PONT DE NEMOURS & CO., AND THE INDEPENDENT PETROLEUM ASSOCIATION OF AMERICA

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Senate Committee on Governmental Affairs, *Study on Federal Regulation*, 95th Cong., 2d Sess. 42 (December 1978) 20

IN THE

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This memorandum is submitted jointly by the American Petroleum Institute ("API"), *et al.*,[1] the Rubber

[1] API files this opposition memorandum on behalf of itself, the National Petroleum Refiners Association, and all petroleum com-

Manufacturers Association ("RMA"), *et al.*,[2] the Chemical Specialties Manufacturers Association, E. I. du Pont de Nemours & Co., and the Independent Petroleum Association of America, in opposition to the petitions for a writ of certiorari filed on behalf of the Secretary of Labor ("OSHA")[3] and the Industrial Union Department, AFL-CIO ("IUD"),[4] asking this Court to review the Fifth Circuit's decision in *American Petroleum Institute* v. *OSHA*, 581 F.2d 493 (1978) (the "API decision"). App. 1a-33a.[5]

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pany respondents in this case specifically: American Petrofina, Incorporated, Atlantic Richfield Company, Cities Service Company, Exxon Corporation, Gulf Oil Company, Marathon Oil Company, Phillips Petroleum Company, Shell Oil Company, South Hampton Oil Company, Standard Oil Company (Indiana), Standard Oil Company of Ohio, Sun Oil Company of Pennsylvania, Sun Oil Company of Delaware, Texaco, Inc., and Union Oil Company of California.

[2] RMA files this opposition memorandum on behalf of itself and all other rubber industry respondents, which are listed at n.1 of a separate joint opposition memorandum filed today. See n.6, *infra*.

[3] Petition for a Writ of Certiorari, filed December 26, 1978, by the Solicitor General on behalf of the United States Department of Labor (hereinafter "OSHA Pet."). The Secretary of Labor is authorized by the Occupational Safety and Health Act of 1970, 29 U.S.C. §§ 651 *et seq.* ("the Act" or "the OSHA Act") to promulgate mandatory occupational safety and health standards. The Secretary's responsibilities in this regard have been delegated to the Assistant Secretary of Labor for Occupational Safety and Health, the head of the Occupational Safety and Health Administration ("OSHA"). 41 Fed. Reg. 25059.

[4] Petition for a Writ of Certiorari, filed December 7, 1978, by the Industrial Union Department, AFL-CIO (hereinafter "IUD Pet."). IUD was an intervenor on the side of OSHA in the proceeding below.

[5] "App." refers to the appendix submitted by IUD in No. 78-911. References to the record are abbreviated as follows: Transcript: "Tr."; Exhibit: "Ex."

QUESTION PRESENTED[6]

OSHA and IUD attempt to lull this Court into accepting review by (i) posing hypothetical questions never decided by the court below (OSHA Pet. 2; IUD Pet. 2), and by (ii) erroneously claiming that the API decision will "cripple[] the Secretary's ability to deal with substances that cause cancer." OSHA Pet. 16 n.9; *see also* OSHA Pet. 14, 19; IUD Pet. 12, 16. But, in reality, the court below decided only a limited issue of first impression critically dependent on the factual record in this case.

In light of this record, which the Fifth Circuit analyzed in detail, the decision below is perfectly sensible. The undisputed facts are that no one has been able to show any cancer hazard from benzene exposure below 100 parts per million ("ppm"), despite exhaustive scientific research and years of practical experience with low-level benzene concentrations. Given these facts, Judge Charles Clark, for the court below, held simply that, before lowering the permissible exposure limit ("PEL") from 10 to 1 ppm, OSHA must develop "rough but educated" estimates of the risks from exposure below 10 ppm and utilize such estimates to show a "reasonable relationship" between the "one-half billion dollar" costs and the lowered risks (i.e., health benefits) attributable to reducing exposure to 1 ppm.

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[6] This memorandum deals exclusively with the decision of the court below setting aside OSHA's permissible airborne exposure limit for benzene. OSHA's Petition raises a second issue regarding dermal exposure provisions which is addressed in a separate Joint Memorandum in Opposition on the dermal exposure issue, filed today on behalf of the same respondents joining in this memorandum. In order to make this presentation as concise as possible, we incorporate by reference the jurisdictional statement and statutory provisions set forth in the dermal exposure brief.

Only by following such a process can OSHA show that reducing the existing 10 ppm standard to 1 ppm is "reasonably necessary" under the OSHA Act.

By any fair reading of the Fifth Circuit's decision, the only question properly before this Court is: Whether the court below correctly held that "substantial evidence does not support OSHA's conclusion that the benefits of [a 1 ppm PEL] are likely to be appreciable," where OSHA cites *no* evidence supporting its "appreciable benefits" finding, and where the best available record evidence shows that "rough but educated" benefits estimates can be, and actually have been, developed for benzene. *See* App. 18a, 19a n.23, 21a.

The Fifth Circuit's resolution of this question does not conflict with the decisions of other circuits. Indeed, in previous cases reviewing OSHA health standards, the issue of estimating health benefits was, for reasons peculiar to the facts of those cases, never even raised by the parties, much less addressed or decided by the reviewing courts. *See* pp. 19-25, *infra.*

Nor will the API decision "cripple" OSHA's regulation of benzene or other toxic substances. The record in this case (not to mention the regulatory experience of other federal health and safety agencies),[7] provides

[7] For example, the Environmental Protection Agency ("EPA") and the Consumer Product Safety Commission ("CPSC") both routinely prepare benefit estimates for substances being regulated. *See* EPA's "Interim Procedures for Regulatory Decisions Involving Suspect Carcinogens," 41 Fed. Reg. 21402 (May 25, 1976), CPSC's "Interim Policy" for Carcinogens, 43 Fed. Reg. 25658, 25664 (June 13, 1978).

Indeed, both EPA and CPSC have drafted risk assessments for benzene. *See* EPA Carcinogen Assessment Group, *Population Risk of Ambient Benzene Exposures* (October 1977) (hereinafter "EPA Benzene Risk Assessment") (submitted to the court below by OSHA itself); CPSC Proposed Regulation of Benzene, 43 Fed. Reg. 21838, 21841 (May 19, 1978) (discussing risk assessment prepared by CPSC's Health Sciences staff). Both risk assessments are currently being reconsidered in light of detailed comments submitted by API and other interested parties.

the basis for further benzene proceedings and confirms that the process specified by the court below is likely to work in future cases as well. Moreover, the important general issue of how to make greater use of benefit estimates in regulating toxic substances is currently the subject of high-level interagency review,[8] and OSHA itself is about to complete a mammoth, "generic" rulemaking proceeding to decide, *inter alia,* how quantitative risk assessments should be utilized in regulating occupational carcinogens.[9]

COUNTERSTATEMENT OF THE CASE

In their respective Statements, OSHA and IUD not only misconstrue and exaggerate the Fifth Circuit's holding and its practical consequences, but, more importantly, they ignore virtually all of the extensive record evidence which prompted the court below to set aside OSHA's 1 ppm PEL for benzene. The purpose of this Counterstatement, therefore, is to summarize the evidence omitted by OSHA and IUD and to explain its critical significance for the limited ruling made by the court below.

[8] *See* p. 29 & n.62, *infra.*

[9] *See* "Proposed Rule for the Identification, Classification and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk," 42 Fed. Reg. 54148 (October 4, 1977), and discussion p. 30 & n.63, *infra.*

A. Background of the Benzene Standard

As they tried unsuccessfully to do in the Fifth Circuit, both OSHA and IUD seek to leave this Court with the erroneous impression that occupational exposure to benzene constitutes an actual health emergency requiring immediate and drastic action. But, in fact, there is no evidence of any cancer hazard from exposure below 100 ppm, and the relatively few workers presently exposed above 1 ppm are adequately protected by the current 10 ppm benzene standard. 29 C.F.R. § 1910.1000 Table Z-2 (1977). Even though the evidence indicates that benzene may be linked to leukemia from exposures above 100 ppm, no workers are currently exposed to such concentrations and no workers are dying of benzene-leukemia.[10]

Rather than being some sort of exotic "poison" (IUD Pet. 11), benzene is actually a common organic compound naturally present in water supplies, animal and plant matter, many foods,[11] and, most significantly, in crude oil, where it occurs in amounts from trace levels to more than one percent by liquid volume.[12] Benzene is also manufactured in the petroleum refining process for use in the petrochemical industry and in the production of gasoline. App. 6a.

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[10] *See* p. 11 & n.26, *infra*.

[11] Testimony of Dr. Herman Kraybill (National Cancer Institute) Ex. 84.B-18, app. A at 2-3, Tr. 1176, 1192-94; Testimony of Edward Baier (National Institute of Occupational Safety and Health), Ex. 84.A at 7, Tr. 749-50, 1132; Mobil Research and Development Corp. Memorandum, Ex. 117.

[12] Testimony of Harold A. Galloway, Ex. 115.A-4 at 2-3, 5-7, Tr. 1465; Testimony of R. J. Comeaux, Ex. 115.A-2 at 2-4.

Because its presence is so widespread, hundreds of thousands of workers, and tens of millions of other persons, including especially motorists, are exposed to small amounts of benzene ranging up to 1 ppm.[13] Notwithstanding this nearly universal exposure to measurable benzene concentrations, no epidemic of leukemia is occurring. Moreover, despite OSHA's effort to portray benzene exposure as a serious health hazard for "some 629,000 workers" (OSHA Pet. 14 n.9), the record shows that, under the current 10 ppm standard, no more than about 30,000 workers are exposed in excess of 1 ppm,[14] and, even among such workers, there is no increased incidence of leukemia. *See* p. 11 & n.26, *infra*.

The history of occupational controls on benzene exposure is recounted by the Fifth Circuit. App. 7a-8a. Although early controls were aimed principally at the non-leukemogenic, toxic effects of benzene exposure, the evidence prior to 1977 also pointed to a relationship between exposure to high concentrations of benzene (in excess of 100 ppm) and leukemia. Taking this evidence into account, a number of scientific bodies, including the National Academy of Sciences, the prestigious International Workshop on the Toxicology of Benzene, and the National Institute of Occupational Safety and Health ("NIOSH"),[15] endorsed the 10 ppm PEL es-

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[13] *See* Exs. 93.A, 93.G-1, 93.G-2 (NIOSH service station exposure data). Natural ambient background levels of benzene approach 0.5 ppm. *See* authorities cited in n.11, *supra*.

[14] Arthur D. Little, Inc., *Economic Impact Statement for Benzene* 1-7 (May 1977) (Ex. 5). Arthur D. Little was OSHA's economic contractor for the benzene standard.

[15] National Academy of Sciences ("NAS"), *A Review: Health Effects of Benzene* ii (June 1976) (Ex. 2-4); International Work-

tablished by OSHA in 1971—which NIOSH termed a "conservative limit" designed to "prevent all adverse effects including leukemia from benzene exposure." [16]

In April 1977, however, the so-called Infante Report was released, finding excess leukemia among pliofilm workers purportedly exposed to very low benzene concentrations during the 1940's.[17] OSHA seized on this report, claiming that it linked leukemia and benzene concentrations "significantly below . . . 10 ppm," [18] and immediately issued an emergency temporary standard ("ETS") under Section 6(c) of the Act, 29 U.S.C. § 655(c), reducing the PEL from 10 to 1 ppm and imposing extensive monitoring, medical surveillance and other requirements.[19]

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shop on the Toxicology of Benzene, *Final Report* 7 (November 11, 1976) (Ex. 17); NIOSH, *Criteria for a Recommended Standard: Occupational Exposure to Benzene* (1974) (Ex. 2-3).

[16] Memorandum of Dr. Herbert E. Christiansen (NIOSH) (Nov. 13, 1974) (Ex. 32.B). NIOSH later recommended a reduction from 10 to 1 ppm in its *Revised Criteria for a Recommended Standard: Occupational Exposure to Benzene* (Aug. 19, 1976) (Ex. 2-5). While IUD highlights this revised recommendation (IUD Pet. 5-6), IUD neglects to add that NIOSH's revision relied almost exclusively on University of North Carolina (UNC) epidemiologic studies which NAS, the authors of the studies, and OSHA itself, all rejected as inconclusive. NAS, *Health Effects of Benzene, supra* n.15 at 13; Testimony of Dr. Herman Tyroler (UNC), Ex. 161 at 2, Tr. 3105, 3114-15; App. 112a.

[17] P. Infante, *et al.*, "Leukemia Among Workers Exposed to Benzene" (April 28, 1977) (Ex. 40).

[18] OSHA Opposition to Stay Pending Judicial Review at 9-10, API v. OSHA, No. 77-1973 (5th Cir., filed June 1, 1977).

[19] 42 Fed. Reg. 22516 (May 3, 1977) (Ex. 1). Thus, IUD's suggestion (IUD Pet. 6) that the ETS was in response to NIOSH's 1976 revised recommendation is inaccurate. *See* n.16, *supra*.

The American Petroleum Institute and nineteen member companies promptly challenged OSHA's ETS in the Fifth Circuit. Petitioners' investigations soon revealed that the workers studied by Infante *et al.* had actually been exposed to very high benzene concentrations well in excess of 100 ppm. Based on this and other information, one judge of the Fifth Circuit granted a stay, which was continued after briefing and oral argument before a three-judge panel of that court.[20] Simultaneously with the issuance of the stay, the case was transferred to the D.C. Circuit which, after further briefing, retransferred to the Fifth Circuit and maintained the stay in effect.[21]

By statute, issuance of an ETS automatically triggered the publication of a proposed revision in the existing permanent benzene standard. 29 U.S.C. § 655(c)(3). Hearings on OSHA's proposed standard (which was essentially identical to the 1 ppm ETS stayed by the courts)[22] began on July 19, 1977. At the hearings, compelling evidence was developed showing that OSHA's 1 ppm proposal was unnecessary and favoring retention of the existing 10 ppm PEL.[23]

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[20] API v. OSHA, No. 77-1973 (5th Cir., Orders dated May 19 and June 6, 1977).

[21] Industrial Union Dep't., AFL-CIO v. Bingham, 570 F.2d 965, 187 U.S. App. D.C. 56 (1977).

[22] 42 Fed. Reg. 27452, 27460-64 (May 27, 1977) (Ex. 4).

[23] Of equal importance were numerous other provisions of the proposed standard supposedly ancillary to the PEL. These provisions required periodic monitoring and medical surveillance at the majority of the nation's *700,000* oil and gas wells, as well as at hundreds of thousands of additional workplaces in pipeline operations, refineries, chemical plants and bulk terminals for marketing refined petroleum products. Testimony of Harold Galloway, Ex.

First, as emphasized by testimony of the Infante authors themselves, the hearings left no doubt that OSHA had gone "off the deep end" by proposing a 1 ppm standard based on the Infante Report.[24] Thus, the record conclusively shows (as OSHA now concedes and the court below found) that the workers studied by Infante were actually exposed to "around 100 ppm during most of the period studied with occasional exposure levels as high as several hundred parts per million." App. 8a n.13, 105a.

But record evidence favoring retention of the current 10 ppm standard went far beyond showing the Infante Report to be just another reported association between very high benzene exposures and an increased incidence of leukemia. For example, a comprehensive reexamination of previous reports linking leukemia and high-level benzene exposure showed that the increased incidences of leukemia reported by Aksoy, Vigliani and Infante—the key data relied on by OSHA—had been completely eliminated once benzene exposures were

115.A-4 at 5-7; App. 148a; Testimony of Keith E. Bailey, Ex. 115.A-1 at 3-5; Testimony of R. J. Comeaux, Ex. 115.A-2 at 4-7; Testimony of John R. Sexton, Ex. 115.A-10 at 4-8, 20-23. Together these requirements comprised approximately two-thirds of the total operating cost of complying with the standard. Testimony of Dr. Richard Zeckhauser, Ex. 115.A-12 at 15. Because essentially all of these workers are already exposed to benzene under 1 ppm, these provisions can fairly be characterized as extraordinarily costly, "busywork" requirements which would yield no health benefits whatsoever. Post-Hearing Brief of API 141-46 (Ex. 217-33) ("API Post-Hearing Br."); App. 148a, 150a, 188a-190a.

[24] Testimony of Ronald Young, Tr. 815-16. Dr. Infante and Edward J. Baier, Deputy Director of NIOSH, also rejected OSHA's interpretation of the study. Tr. 1137-40.

reduced below 100 ppm.[25] The same conclusion emerged from four separate, large-scale studies (totaling well over 60,000 workers), each showing no unexpected incidence of leukemia among workers exposed for many years to low concentrations of benzene.[26]

When considered together, this record establishes a far greater likelihood of a practical threshold for safe exposure to benzene than for any chemical substance previously regulated by OSHA.[27] But respondents and other hearing participants did not rest their case exclusively, or even principally, on this uniquely strong showing of a threshold.

Specifically, respondents argued that OSHA must assess and consider the extent of the leukemia risk from benzene exposure below 10 ppm before reducing the

[25] The details of this reexamination were accepted by the court below. App. 8a n.13. They are described in greater detail in API Post-Hearing Br., *supra* n.23 at 56-57, 61-65.

[26] *See*, Thorpe, *Epidemiologic Survey of Leukemia in Persons Potentially Exposed to Benzene*, Ex. 2-34; Tabershaw/Cooper, *A Mortality Study of Petroleum Refinery Workers*, Ex. 2-59; Tabershaw/Cooper, *Follow-up*, Ex. 115.B-3 at ex. 3; Stallones & Syblik, *Report on Mortality from Leukemia*, Ex. 115.C-2; J. W. Lloyd, "Long-Term Mortality Study of Steel Workers, V," Ex. 113; C. K. Redmond, *et al.*, "Long-Term Mortality Study of Steel Workers, VI," Ex. 217-27.D; C. K. Redmond, *et al.*, "Cancer Experience Among Coke By-Product Workers," Ex. 217-27.C. The results of these studies are summarized in API Post-Hearing Br., *supra* n.23 at 65-75; and Testimony of the Principal Representative of the American Iron and Steel Institute 7-10 (Ex. 156-1).

In addition to these studies reflecting actual experience with benzene exposure, more than 35 post-1970 scientific studies were presented at the hearing which indicated the existence of thresholds for safe exposure to carcinogens in general and benzene in particular. API Post-Hearing Br., *supra* n.23 at 80-91 and app.

[27] *Compare* p. 21 & n.45, *infra*.

PEL to 1 ppm.[28] Respondents contended that once this is done, and even assuming no threshold (and hence some leukemia risk below 100 ppm), the risk from exposure below 10 ppm is likely to prove minimal.

The record unquestionably shows that OSHA has both the capability and resources to perform such analysis. For example, OSHA's economic contractor for the benzene standard, Arthur D. Little, Inc., testified that it was capable of developing such estimates, but that OSHA never permitted it to do so.[29] Similarly, the record shows that other agencies routinely assess risks and benefits in comparable situations,[30] and that EPA was, in fact, preparing a risk assessment for benzene.[31]

While exact quantification of the risk at low levels may be "on the frontiers of scientific knowledge," [32] economists at the hearings uniformly testified that even an imprecise risk estimate would be "of immense value" in assessing the reasonableness of OSHA's 1

[28] In this contention, respondents were supported by government agencies such as the President's Council on Wage and Price Stability and the Department of Health, Education and Welfare. App. 160a; Letter of Charles Custard, Director, HEW Office of Environmental Affairs (July 12, 1977) (Ex. 205.A).

[29] Testimony of Dr. Lawrence Partridge of Arthur D. Little, Inc., Tr. 512, 515, 518.

[30] Among the agencies mentioned were the Nuclear Regulatory Commission ("NRC") and the National Highway Traffic Safety Administration ("NHTSA"). Testimony of Dr. Richard Zeckhauser, Tr. 2108; Testimony of Dr. Richard Wilson, Tr. 2710, 2750-51. *See also* n.7, *supra;* n.63, *infra.*

[31] Testimony of James Durham (EPA Office of Air Quality Planning and Standards), Tr. 2356. *See* nn. 35, 57, *infra.*

[32] Testimony of Dr. Richard Zeckhauser, Tr. 2192.

ppm standard.[33] A preliminary risk assessment prepared by Dr. Richard Wilson of Harvard University dramatically illustrated this point. Using worst-case methodology, Dr. Wilson calculated that OSHA's 1 ppm standard might prevent, at most, two cases of cancer every six years at a cost of $300 million per case.[34] Although Dr. Wilson's estimates were admittedly preliminary, it is significant that their general accuracy was later confirmed by by EPA's Benzene Risk Assessment, submitted by OSHA to the court below.[35]

[33] Testimony of Dr. Richard Zeckhauser, Ex. 115.A-12 at 12, *passim*, Tr. 2104-2112, 2141-2202, *passim;* Testimony of Dr. Richard Wilson, Ex. 149.B at 27, Tr. 2706; Testimony of Dr. James Henderson, Ex. 115.A-5 at 6, 10.

Dr. Zeckhauser, for example, repeatedly emphasized that *ranges* and *upper bounds* of estimated health benefits would be "of immense value," and more than adequate for a useful assessment of the cost-effectiveness of OSHA's benzene standard. Testimony of Dr. Richard Zeckhauser, Ex. 115.A-12 at 12, Tr. 2117, 2153, 2157, 2167-68, 2169-70, 2186.

[34] Testimony of Dr. Richard Wilson, Tr. 2749-50, Ex. 149.B at 19-29.

[35] App. 19a n.23. OSHA originally submitted the EPA Benzene Risk Assessment (n.7, *supra*) to the court below in an effort to discredit the preliminary Wilson estimate. In answer, respondents before this Court provided an analysis showing that the EPA's and Wilson's estimates were virtually identical once EPA's estimates were converted from the *environmental* context (involving continuous, life-time (70 year) exposure of the entire U.S. population) to the *occupational* context (involving exposure of 30,000 workers to over 1 ppm for one-third of each of about 240 workdays per year for a *work*life (40 years)). As converted to the occupational context, EPA's risk assessment projects that OSHA's 1 ppm standard will prevent *one case* of acute, non-lymphocytic leukemia (the specific type of leukemia linked to benzene exposure) *every 15 to 38 years. See* Affidavit of Steven H. Lamm, filed June 21, 1978.

B. The Final Standard

Despite this record evidence, OSHA's final benzene standard adopted a 1 ppm PEL and broadened even further the expensive, and largely unnecessary, ancillary requirements of the standard.[36] Although OSHA recognized the Infante Report as simply another high-exposure study (App. 104a-107a), it failed even to address most of the practical threshold evidence presented at the hearings. Instead, OSHA retreated to a conclusive "policy judgment" that there is no threshold for safe exposure to any carcinogen, and that it is "therefore" necessary to reduce benzene exposure to the lowest level technologically possible consistent with the continued existence of the industries regulated by the standard. App. 124a.

Based on this "policy judgment", OSHA assumed —rather than demonstrated by substantial evidence— that a 1 ppm PEL was required. Thus, OSHA did not (and could not) cite any record evidence documenting a leukemia risk under 10 ppm. Nor did OSHA attempt to estimate the risk (if any) below 10 ppm. App. 158a-163a. Nevertheless, OSHA purported to find justification for its 1 ppm PEL by speculating that benefits "are likely to be appreciable." App. 162a.

Although conceding the utility of benefit estimates,[37] OSHA never addressed the record evidence on this

[36] Some aspects of the expanded coverage of the final standard, and subsequent amendments thereto, are discussed in respondents' Joint Memorandum in Opposition on the dermal exposure issues, filed today. *See also* n.23, *supra*.

[37] OSHA stated that the requirements of Section 6(b)(5) of the Act "*do*[ ] *not mean* . . . that a systematic evaluation of costs and benefits is not to be encouraged within the limits of the estimation techniques." App. 159a (emphasis added).

issue. For example, OSHA stated that it was "unwilling to rely" on Dr. Wilson's estimate of low-exposure risks, but gave no reasons for its "unwillingness" except to recite the results of the high-exposure Infante Report. App. 161a.[38] To be sure, OSHA did conclude, without reference to *any* record evidence whatsoever, that "a *precise* quantitative relationship cannot be established," and that "it is impossible to *precisely* quantify the anticipated benefits." App. 160a, 162a (emphasis added). But OSHA never addressed the comments of industry and government participants who noted that precision may not be possible but urged that rough but useful estimates could be—and have been—prepared for benzene.

OSHA's final standard was immediately challenged, with petitions for review filed in various circuits consolidated in the Fifth Circuit. In addition to the 1 ppm PEL, petitioners challenged the necessity for the sweeping and costly monitoring, labeling, training, medical surveillance and related provisions contained in the final standard.[39] Based on the irreparable injury which would result from the implementation of these provisions, as well as an overall likelihood of success on the merits, the benzene standard was stayed pending review following argument before the Fifth Circuit on April 18, 1978. App. 10a.

[38] App. 161a. OSHA did not explain how, absent a quantitative risk assessment, the incidence of leukemia in the 100 ppm Infante Study can be related to the risk under 10 ppm.

[39] *See* nn.23, 36, *supra*. The validity of these provisions was never reached by the court below because they were set aside as ancillary to the unsupported 1 ppm PEL. App. 21a-22a, 33a.

C. The Opinion Below

The court of appeals announced its decision on the merits on October 5, 1978. The crux of its holding was that "*substantial evidence does not support* OSHA's conclusion that the *benefits* [of a 1 ppm PEL] are likely to be *appreciable.*" App. 18a (emphasis added). According to the court, "OSHA merely assumed that benefits from the reduction [of the existing standard] 'may be appreciable' " (App. 17a), without ever responding to record evidence that the benefits would be minute or employing the admitted capability of its own contractor to estimate benefits. As a result, the court set aside OSHA's 1 ppm PEL because "Congress intended for OSHA to regulate on the basis of more knowledge and *fewer assumptions* than *this record* reflects." App. 21a (emphasis added).

The path that the court followed in reaching this "substantial evidence" determination is best seen from the two separate contentions made by petitioners below. Thus, as before OSHA, petitioners challenged OSHA's finding "that no known safe level for benzene exposure exists." App. 13a. But petitioners' "principal argument" was that "substantial evidence and the best available evidence do not show that reduction of the permissible exposure limit from 10 ppm to 1 ppm is reasonably necessary to provide safe or healthful employment and places of employment." App. 10a-11a.

The court ultimately rejected petitioners' first argument even though it largely accepted petitioners' contention that the factual evidence pointed to a "safe level for benzene exposure" well in excess of 10 ppm. App. 8a n.13, 13a n.20. The reason for this was the court's conclusion (consistent with previous cases) that "[t]he

divided opinion in the scientific community over the existence or not of safe threshold levels to carcinogens provides substantial evidence that would support the finding that exposure to benzene at the present level of 10 ppm poses some leukemia risk." App. 18a.

But regarding petitioners' "principal" argument, the Court was unwilling to make the further assumption that the benefits of a reduction from 10 to 1 ppm would be "appreciable"—especially where the record evidence showed no actual hazard below 100 ppm and strongly indicated that any benefits below 10 ppm would be minimal. App. 18a-19a & n.23. In the court's words, OSHA's no threshold finding, even if accepted, "does *not* yield the conclusion that *measurable* benefits will result, and *OSHA is unable to point to any studies or projections supporting such a finding.*" App. 18a (emphasis added).

The court tested these facts against the legal criteria for OSHA standards found in Sections 3(8) and 6(b)(5) of the Act. Based on these statutory provisions, the court concluded that OSHA may not simply assume, without factual foundation, that the benefits of a reduction to 1 ppm will be "appreciable," and use such an unsubstantiated assumption to sustain a standard at that level.

In section 3(8), the term "occupational safety and health standard" is defined as provisions which are "reasonably necessary or appropriate to provide safe or healthful employment and places of employment." 29 U.S.C. § 652(8). The court concluded that, on this record, OSHA could not show by substantial evidence that its benzene standard is *"reasonably necessary"* to achieve this end without at least *"rough but educated*

estimates of the extent of benefits expected from reducing the permissible exposure level from 10 ppm to 1 ppm." App. 21a (emphasis added).

An equally compelling basis for reaching this result was provided by section 6(b)(5). As summarized by the court:

> [T]hat section requires standards to be *feasible*, and it contains a number of *pragmatic limitations* in the form of specific kinds of information OSHA must consider in enacting standards dealing with toxic materials. Those include "the *best available evidence*," "research, demonstrations, experiments, and such other information as may be appropriate," "the latest available scientific data in the field," and "*experience* gained under this and *other health and safety laws*."

App. 16a (emphasis added).

The court concluded that, "[b]y requiring consideration of such kinds of information, Congress provided that OSHA regulate on the basis of knowledge rather than the unknown" (App. 20a)—especially where, as here, the "best" (indeed, the *only*) "available evidence" of the risk posed by benzene exposure below 10 ppm consisted of the EPA and Wilson risk assessments (App. 19a n.23), and the regulatory "experience" of "other health and safety" agencies showed that at least "rough but educated estimates of the extent of benefits" were possible. App. 21a.

REASONS FOR DENYING THE WRIT

I. The API Decision Correctly Resolves A Question Of First Impression Never Before Raised, Much Less Addressed Or Decided, In Previous OSHA Health Standard Cases.

The API decision presents a question of first impression, the resolution of which is closely tied to the unique factual record for benzene. Although petitioners below, like petitioners in two of the three cases cited by OSHA and IUD,[40] argued that there was a threshold level for safe exposure to benzene, the court (consistent with the *SPI* and *AISI* courts) rejected petitioners' contention. App. 18a. But having turned aside the safe threshold argument, the court went on to address a separate question never raised (and therefore never decided) in previous occupational health standard cases —namely, how OSHA should regulate a substance showing minimal (if any) risks below the existing standard where there is a record basis for an imprecise, but useful, estimate of the benefits of reducing the PEL.

For example, *Industrial Union Department* v. *Hodgson* was a challenge by labor unions (*not* by employers) who *accepted* the PEL set by OSHA's asbestos standard but attacked the standard's four-year compliance timetable.[41] Thus, the question of whether OSHA must

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[40] Industrial Union Department, AFL-CIO v. Hodgson, 499 F.2d 467, 162 U.S. App. D.C. 331 (1974) ("Hodgson"); Society of the Plastics Industry ("SPI") v. OSHA, 509 F.2d 1301 (2d Cir.), *cert. denied*, 421 U.S. 922 (1975); American Iron and Steel Institute ("AISI") v. OSHA, 577 F.2d 825 (3d Cir. 1978), *petitions for cert. pending*, Nos. 78-918, 78-919.

[41] The petitioning unions' contentions are set forth at the outset of the opinion, where the court makes clear that no issue concerning the asbestos PEL was raised. 499 F.2d at 470, 162 U.S. App. D.C. 334.

provide an estimate of health benefits simply was not involved in *Hodgson*. OSHA's and IUD's assertions of a "conflict" hinge on nothing more than the early part of the *Hodgson* opinion where the court, in dicta, discusses theoretically the application of the statutory "substantial evidence" test (29 U.S.C. §655(f))—a passage having nothing to do with the completely different question decided by the Fifth Circuit. 499 F.2d at 474-76, 162 U.S. App. D.C. 338-40.[42]

Moreover, the factual record before the *Hodgson* court demonstrates dramatically why employers never challenged the asbestos standard, much less raised the issue of health benefits. There, the evidence strongly suggested that *40 to 60 percent* of workers historically exposed to asbestos were expected to die of asbestosis or cancer,[43] and that *"significant disease"* was found in workers exposed *well below* the *previous* national consensus standard for asbestos.[44]

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[42] The court explicitly characterizes this passage as an abstract "example" of how it would apply the substantial evidence test, 499 F.2d at 475, 162 U.S. App. D.C. 339, and refers to its own preliminary ruminations as "analytical background," 499 F.2d at 478, 162 U.S. App. D.C. 342.

[43] Brief for Petitioners at 6, IUD v. Hodgson (D.C. Cir. No. 72-1713, filed March 29, 1973), *quoting Legislative History of the Occupational Safety and Health Act of 1970*, 92d Cong., 1st Sess. 412-13, 1002 (1971) (remarks of Senator Williams and Congressman Daniels).

[44] Brief for Petitioners at 47, IUD v. Hodgson (D.C. Cir. No. 72-1713, filed March 29, 1973) (emphasis added). Indeed, an unpublished independent analysis of the asbestos standard concluding that it will *prevent 1,596 deaths per year* was recently cited by the Senate Committee on Governmental Affairs in its *Study on Federal Regulation*, 95th Cong., 2d Sess. 42 (December, 1978).

Nor do the *SPI* or *AISI* cases conflict with the API decision. Both involved challenges to OSHA's exposure limits (for vinyl chloride and coke oven emissions, respectively) on the ground that there was no health basis for OSHA's standard because a higher exposure level was supposedly "safe."[45] Like the court below, the Second and Third Circuits rejected this argument. *SPI* v. *OSHA*, 509 F.2d at 1308; *AISI* v. *OSHA*, 577 F.2d at 831-32. In contrast to the API petitioners, however, petitioners in neither the *SPI* nor *AISI* cases raised OSHA's legal obligation to assess benefits once their safe threshold level contentions were rejected.[46]

Again, the factual records of the vinyl chloride and coke oven emissions cases leave little doubt why the contention that OSHA must assess benefits was never raised. The record before the Third Circuit in *AISI* included risk assessments predicting that *hundreds* of lives could be saved *each year* by significant reductions

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[45] In each case, employer petitioners relied on a single epidemiologic study revealing that workers exposed to levels above the challenged PEL showed no unusual incidence of cancer. *See* SPI v. OSHA, 509 F.2d at 1308; AISI v. OSHA, 577 F.2d at 827; Brief for All Petitioners Other Than Republic Steel Corp. and CF&I Steel Corp. at 15-17, and Brief for Petitioner Republic Steel Corp. at 34-35, AISI v. OSHA (3d Cir. No. 76-2358 *et seq.*, both filed May 9, 1977).

Petitioners in SPI and AISI also argued that the levels set by OSHA were technologically infeasible and likely to affect significantly the financial viability of the petitioners' businesses. These contentions were not made in the benzene case.

[46] Without any citation to the opinion, OSHA incorrectly asserts that the *AISI* decision "explicitly" rejects this separate contention. OSHA Pet. 13. In fact, OSHA's claim finds no support in either the court's opinion or the briefs of the parties.

in exposure to coke oven emissions.[47] Similarly, the Second Circuit's *SPI* opinion summarizes what the court called the "morbid" history under the previous 1971 vinyl chloride standard, including thirteen recent deaths from angiosarcoma of the liver, an "exceptionally rare" cancer. 509 F.2d at 1305-06.[48] In addition to these recent deaths, the record also included a low-exposure animal study demonstrating that vinyl chloride was, in the court's words, a "very virulent carcinogen." *Id.* 1308.[49]

In short, the question of whether OSHA must make a "rough but educated estimate[] of the extent of bene-

[47] *See* 41 Fed. Reg. 46750 (October 22, 1976) (Ex. 2.B-275). Risk assessments regarding the coke oven standard were performed by OSHA's economic impact contractor and the President's Council on Wage and Price Stability. It is impossible to say whether these risk assessments would satify the API decision; however, the far greater health hazards shown by these assessments explains why, in contrast to benzene, the issue of OSHA's obligation to estimate the health benefits of its action was never raised by the parties.

[48] Nine of these deaths occurred within a five-month period immediately preceding OSHA's proposal of the standard challenged in *SPI*. 509 F.2d at 1306.

[49] This study showed that of 200 mice exposed to 50 ppm vinyl chloride, 100 died within 11 months, and in each case where a gross post-mortem pathologic examination was made, cancer was found. *See* 39 Fed. Reg. 35891 (October 4, 1974) (Ex. 2.B-276). While the incidence rate for mice may bear an imperfect correlation with the incidence in humans, this 50 percent mortality rate is striking nevertheless when compared to the "exceptionally rare" incidence of liver angiosarcoma in the general population—one in 50,000, or .002 percent. 509 F.2d at 1306. Several witnesses in the benzene hearings, including Dr. Herman F. Kraybill of the National Cancer Institute, testified that vinyl chloride is a much more potent carcinogen than benzene, and the two substances should not be considered in the same category. *E.g.*, Testimony of Dr. Herman F. Kraybill, Tr. 1239-40; Testimony of Dr. Richard Wilson, Tr. 2746-48.

fits," was never argued by the parties nor decided by the courts in any of the previous cases. The court below distinguished these cases both on the grounds that they "were decided on their own records," and that they did not address "what Congress meant by requiring the conditions imposed by standards to be reasonably necessary to provide safe or healthful places of employment." App. 21a. Moreover, in contrast to the extraordinary health hazards discussed in *Hodgson, SPI* and *AISI*, the court emphasized that, with respect to benzene, "OSHA is *unable* to point to *any empirical evidence* documenting a leukemia risk at 10 ppm" or "to *any studies* or *projections* supporting . . . a finding" that "*measurable* benefits will result" from its 1 ppm standard. App. 18a (emphasis added).

Accordingly, it made perfect sense for the Fifth Circuit to conclude that "Congress intended for OSHA to regulate on the basis of more knowledge and fewer assumptions than this record reflects." App. 21a. For to require any less than the limited showing suggested by the Fifth Circuit would give OSHA "unbridled discretion"—no matter how immaterial (or speculative) the risk or how great the cost—to impose whatever controls possible so long as they do not lead to widespread industry shut-downs. App. 15a.

Such a blank check for OSHA simply cannot be squared with the legislative history or purpose[50]

[50] Section 2(b) states Congress' "purpose and policy" to be "to assure *so far as possible every* working man and woman in the Nation safe and healthful working conditions." 29 U.S.C. § 651(b) (emphasis added). As Dr. Richard Zeckhauser repeatedly stressed at the hearings, unless OSHA uses risk assessments to formulate standards which achieve "the greates. health gain per dollar expended," the statutory purpose will be frustrated because fewer

of the Act.[51] Nor can it be reconciled the "reasonably necessary" requirement of Section 3(8) or the "pragmatic limitations" of Section 6(b)(5). OSHA's argument that Section 6(b)(5) forbids consideration of benefits cannot withstand analysis,[52] because Section 6(b)(5) affirmatively requires that OSHA standards be "based on" the "best" and "latest" "available evi-

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resources will remain to combat more serious hazards and accordingly "we will find that we have achieved less for health and safety than we could have," Testimony of Dr. Richard Zeckhauser, Ex. 115.A-12 at 4. See also App. 13a-14a, where the court below discusses this contention.

[51] *See* Turner Co. v. Dep't of Labor, 561 F.2d 82 (7th Cir. (1977). In *Turner*, the Seventh Circuit, relying on a "thorough" analysis of the legislative history (561 F.2d at 85), adopted an interpretation of the Act closely similar to that of the court below. The *Turner* court held that, in the context of an enforcement action, the term "feasible" in an OSHA noise standard must be interpreted as requiring a determination that compliance costs are justified by health benefits in order to pass muster under "the clear intent of Congress and the purpose of the . . . Act." 561 F.2d at 83.

[52] *Compare* n.37, *supra*. Where Congress has intended that absolute health protection be afforded, regardless of the relative costs and health benefits, it has done so in unmistakable terms, as in the "Delaney Clause" of the Food, Drug, and Cosmetic Act. 21 U.S.C. § 348(C)(3)(a).

OSHA suggests the converse—that where Congress intends that costs and benefits be considered, "it has done so explicitly." OSHA Pet. 17. But the example OSHA cites, the Consumer Product Safety Act ("CPSA"), 15 U.S.C. § 2051 *et seq.*, disproves OSHA's thesis. Nowhere in the CPSA is there an explicit requirement that health benefits be considered. Nevertheless, two courts of appeals have held, relying on a "reasonably necessary" requirement in the CPSA (which the court below called "precisely similar" to Section 3(8) of the OSHA Act (App. 15a)), that standards under the CPSA must be based on a consideration of health benefits. Aqua Slide 'N' Dive v. CPSC, 569 F.2d 831 (5th Cir. 1978); D. D. Bean & Sons v. CPSC, 574 F.2d 643 (1st Cir. 1978).

dence," and on "experience gained under . . . other health and safety laws." In this case, risk assessments, such as those prepared by Dr. Wilson and EPA, constitute the "best"—indeed, the *only*—"available evidence" concerning the leukemia risk (if any) posed by benzene exposure below 10 ppm. Similarly, the regulatory "experience" of virtually every other federal health and safety agency shows that similar rough estimates are routinely prepared and used in regulating toxic substances such as benzene.

II. The Fifth Circuit's Requirement That OSHA Make "Rough But Educated" Benefit Estimates Is Workable In Practice And Will Promote Sensible Regulation Of Benzene And Other Substances.

OSHA and IUD advance an exaggerated reading of the decision below and predict drastic regulatory paralysis if the Fifth Circuit is not immediately reversed.[53] Simply stated, OSHA and IUD appear to argue: (i) that the Fifth Circuit imposed "a cost-benefit test" requiring OSHA to demonstrate that a lower exposure level "saves enough lives" to be "commensurate with its known costs" (OSHA Pet. 2, 9; *see also* OSHA Pet. 10, 13, 19); (ii) that OSHA must determine "the *exact* relationship between decreasing levels of expo-

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[53] Curiously, OSHA also attempts before this Court to justify its 1 ppm standard based on the non-leukemogenic, toxic effects of benzene exposure. OSHA Pet. 6, 16 n.9. This belated attempt to reconstruct OSHA's rationale for a 1 ppm standard is directly contrary to the opening sentence of the preamble to the standard, which concedes that: "This standard is based on OSHA's determination . . . that employee exposure to benzene presents a cancer hazard—specifically, the hazard of developing leukemia." App. 67a. Accordingly, the court below correctly held that any effort by OSHA's lawyers to rely on benzene's non-leukemogenic, toxic effects is a "post hoc rationalization." App. 22a-23a.

sure and disease" (OSHA Pet. 8, 9, 13; IUD Pet. 11, 15); and (iii) that such a "precise relationship" cannot be calculated and, as a result, OSHA will be precluded "from regulating [benzene and] many of the other carcinogens present in the workplace" (OSHA Pet. 9, 14, 16, 19; IUD Pet. 16, 18).[54]

This extreme position cannot be supported by either the court's opinion or the record of this case.

The first two points can be dispensed with quickly. Nothing could be plainer than the court's own statement that "the agency does not have to conduct an elaborate cost-benefit analysis." App. 17a. Moreover, the meaning of the expression "reasonable relationship" was left for later amplification because OSHA's failure to assemble an adequate record "makes it impossible to assess the reasonableness of the relationship between expected costs and benefits" here. App. 21a. While it is premature to say how benefits and costs are to be compared under the API decision, it is clear that, even respecting the requirement that OSHA estimate benefits, the court contemplated something short of

[54] OSHA's exaggerated fears of regulatory paralysis as a result of the API decision bear a haunting resemblance to its contentions in Marshall v. Barlow's, Inc., 436 U.S. 307 (1978). In *Barlow's*, this Court ruled that under the Fourth Amendment, OSHA inspections may not be conducted over an employer's objection without a warrant. OSHA's Jurisdictional Statement in *Barlow's* claimed that "the effectiveness of [OSHA's] inspection system would largely be nullified" by such a requirement. Jurisdictional Statement at 10-11, Marshall v. Barlow's, Inc., No. 76-1143 (Sup. Ct., filed Feb. 17, 1977). OSHA made similar claims on the merits. 436 U.S. at 316. The Court, however, was "unconvinced" by these dire predictions. *Id.* 316-20. Subsequently, OSHA issued regulations to implement the *Barlow's* decision. 43 Fed. Reg. 59839 (December 22, 1978).

"exact" or "precise" estimates—namely, "rough but educated estimates of the extent of benefits." App. 21a.

The evidence proving OSHA's capability to make such estimates is uncontradicted. OSHA's own contractor, A. D. Little, admitted that it could prepare an estimate of benefits and offered to do so. App. 19a n.23.[55] One witness, Dr. Wilson of Harvard, actually prepared a preliminary risk assessment showing that OSHA's standard would save, at most, two lives every six years at the cost of three hundred million dollars each.[56] EPA reached a similar conclusion in a risk assessment in preparation during the OSHA hearings and later submitted by OSHA to the court of appeals.[57]

[55] OSHA now complains for the first time that its contractor "did not offer to demonstrate how such a study could be done." OSHA Pet. 15 n.9. The complete answer is that OSHA *never asked*. *See* Industrial Union Dep't v. Hodgson, 499 F.2d at 480 (remanding OSHA's four-year timetable for compliance with the asbestos standard for lack of an adequate record, relying on OSHA's failure to cross-examine expert witnesses on this issue and stating: "the lack of more specific information may be partially attributable to the Secretary's failure to seek it.").

[56] *See* p. 13 & n.34, *supra*. Even though OSHA offered no reasons for rejecting Dr. Wilson's estimate in the preamble to the standard (*see* p. 15 & n.38, *supra*), OSHA's brief now complains that Dr. Wilson supposedly never submitted the basis for his calculations. OSHA Pet. 15 n.9. But OSHA never offers a single substantive criticism of Dr. Wilson's estimate, even though he carefully detailed his technique during three hours of cross-examination by OSHA, NIOSH and union representatives at the hearings. Tr. 2717-2827.

Nor is there any basis for OSHA's unjustified attempt to portray Dr. Wilson as a mere "physicist." In fact, Dr. Wilson is head of Harvard's Energy and Environmental Policy Center and is a leading expert on the techniques of quantitative risk assessment. Testimony of Dr. Richard Wilson, Ex. 149.B at 2.

[57] In light of Dr. Lamm's analysis showing that the EPA estimate is virtually identical to that of Dr. Wilson (*see* n.35, *supra*),

Under these circumstances, there is ample basis for further proceedings on benzene consistent with the court's opinion. Indeed, as an alternative to further agency proceedings, review by this Court is both unnecessary and undesirable. The previous 10 ppm standard remains in effect and, as demonstrated by the record evidence, is fully adequate to protect those workers (about 30,000) who would be exposed to between 10 and 1 ppm benzene during the pendency of additional agency and court proceedings.[58] Moreover, in the inter-

OSHA's lawyers now attempt to discredit even EPA's estimates by grossly misstating EPA's findings and by arguing that they "are not sufficiently precise." OSHA Pet. 15 n.9. In fact, while EPA acknowledged some margin of error, it pointed out that the model it chose was "expected to give an *upper limit* to the estimated risk," and concluded that the *actual* risk "is not likely to be higher" than its estimate, "but it could be lower." EPA Benzene Risk Assessment, *supra* n.7 at 1, 2 (emphasis added). Thus, Dr. Lamm's conversion of the EPA estimate to the occupational context likely represents the *maximum* health savings from the benzene standard.

[58] As previously noted, the courts have uniformly found a stay of the 1 ppm standard to be in the public interest. *See* p. 9 & n.20, p. 15, *supra*.

Nevertheless, IUD would mislead the Court into believing that a health emergency presently exists. IUD notes an estimate of 250 benzene leukemia cases in the United States (IUD Pet. 8), but neglects the author's critical qualification that *all* of these cases "were regarded as the consequence of *heavy* exposure to benzene vapor" many years ago. Statement of Dr. James H. Jandl, Ex. 217-26.B at 103 (emphasis added). OSHA similarly attempts to confuse the Court by erroneously stating that, under EPA's risk assessment, "exposure of the whole population to [benzene] levels even as low as one part per billion for only 24 hours would cause between 30 and 80 cases of leukemia yearly." OSHA Pet. 15, n.9. In fact, the EPA estimate was expressly based on *continuous lifetime* exposure, *not* a single 24-hour episode of exposure. EPA Benzene Risk Assessment, *supra* n.7 at 5, 7, 13. *See also* nn.35, 57, *supra*.

est of avoiding piecemeal litigation, further agency proceedings are a superior alternative since they will allow OSHA to reconsider the many issues pertaining to other provisions of the standard never reached by the court below because the underlying 1 ppm PEL was set aside. App. 21a.[59]

Nor is there any basis for OSHA's prediction of a general regulatory paralysis if the API decision is not immediately reviewed. The court below necessarily spoke only to the record before it. But even on this record, there are strong reasons for believing that the API decision is both workable and desirable as a means of allowing OSHA to distinguish between more or less potent carcinogens and more or less pressing matters for regulatory attention.[60]

Virtually every other federal health and safety agency, including EPA, CPSC, FDA, and NHTSA, already prepares the type of "rough but educated" benefit estimates that OSHA refuses to make for benzene.[61] Moreover, the underlying question of how to improve the use of quantitative risk assessments is currently the subject of a high-level interagency review.[62] And

[59] *See* p. 9 & n.23, p. 15 & n.39, *supra*.

[60] Significantly, OSHA concedes that risk and benefit estimation techniques are useful for this purpose. OSHA Pet. 17 n.10. OSHA takes the wholly illogical stance, however, that although benefit estimates are "an important decision making tool" in deciding to change an existing standard, their use is absolutely prohibited in deciding what level of regulation is appropriate. Nothing in section 6(b)(5) compels this absurd result. *See* pp. 23-25, nn. 50-52, *supra*.

[61] *See* p. 4 & n.7, 12 & n.30, *supra*.

[62] *See* 42 Fed. Reg. 54857 (October 11, 1977) (establishing an Interagency Regulatory Liaison Group ("IRLG") consisting of

OSHA itself is presently conducting an exhaustive examination, encompassing nearly three months of agency hearings, concerning how to regulate occupational carcinogens, including consideration of the role to be played by quantitative risk assessments.[63]

In short, there is every reason to believe that OSHA has the capability of complying with the API decision in any further proceedings on benzene. Indeed, the progressive and sensible nature of the API decision is confirmed by the "experience" of "other health and safety agencies," which (together with OSHA itself) are now developing comprehensive policies for using risk and benefit estimates to decide whether and how to regulate the large number of substances, of widely varying

OSHA, EPA, FDA and CPSC). EPA Administrator Douglas M. Costle has recently stated that "a major goal" of the IRLG is the "[d]evelopment and coordination of a national cancer policy." Bureau of National Affairs, *Environment Reporter*, Vol. 9, No. 37, at 1706 (January 12, 1979).

[63] *See* n.9, *supra*. In nearly three months of hearings, numerous federal health and safety agencies including the Food and Drug Administration ("FDA"), the National Cancer Institute, EPA and CPSC urged OSHA to assess benefits as required by the court below. The President's Council on Wage and Price Stability urged not only that risk assessments be prepared but also that they are required under the OSHA Act. Report of the Regulatory Analysis Review Group of the Council on Wage and Price Stability on OSHA's "Cancer Policy" Proposal 7, 18-21, 24-30 (October 24, 1978) (OSHA Public Docket No. H-90).

potencies, thought to cause cancer.[64] Accordingly, the better course is to let these developments take their natural course and to allow the meaning and practical consequences of the API decision to be amplified by other court of appeals decisions on different factual records.[65]

[64] For example, NIOSH has published a list of 2,415 potential occupational carcinogens, of which 1,905 substances "were selected on the basis of reported neoplastic or carcinogenic effects." NIOSH, *Suspected Carcinogens: A Subfile of the NIOSH Registry of Toxic Effects of Chemical Substances*, 2nd Edition, Herbert E. Christensen (Ed.), HEW Publication No. (NIOSH) 77-149 (December 1976). These substances may differ enormously in carcinogenic potency. The record in this case, for example, shows that benzene is 10,000 times weaker than aflatoxin, a potent carcinogen present in peanuts and peanut butter at tolerance levels set by FDA. Testimony of Dr. Richard Wilson, Tr. 2706, 2721-23, 2726; 39 Fed. Reg. 42748 (December 6, 1974).

[65] This Court may benefit from the resolution of three OSHA health standards presently pending in two circuits (IUD Pet. 15). For example, the issue of how benefits and costs must be weighed in establishing a "reasonable relationship"—an issue not resolved finally by the court below (*see* p. 27, *supra*)—has been raised in pending review proceedings on OSHA's cotton dust standard. Brief of the American Textile Manufacturers Institute, *et al.* at 67-81, AFL-CIO v. Marshall, D.C. Cir. Nos. 78-1562 *et seq.* In another case (arsenic), the petitioners submitted the API decision after oral argument. OSHA takes the position that the API benefit estimation issue is not before the court. Letter dated October 31, 1978 from Lorelie Borland (OSHA counsel) to Emil E. Melti, Jr. (Clerk of the 9th Circuit), Asarco Inc., *et al.* v. OSHA (9th Cir. No. 78-1959). The third case (lead) was recently transferred by the Third Circuit to the D.C. Circuit. Briefs on the merits have not yet been filed.

CONCLUSION

For the foregoing reasons, the petitions for a writ of certiorari filed by OSHA and IUD should be denied.

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1978

No. 78-911

INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, *ET AL.*,
Respondents.

No. 78-1036

RAY MARSHALL, SECRETARY OF LABOR,
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, *ET AL.*,
Respondents.

On Petitions For A Writ of Certiorari To The United States Court Of Appeals For The Fifth Circuit

JOINT MEMORANDUM IN OPPOSITION FOR RESPONDENTS

THE RUBBER MANUFACTURERS ASSOCIATION, INC., *ET AL.*,
AMERICAN PETROLEUM INSTITUTE, *ET AL.*,
CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION,
E. I. DU PONT DE NEMOURS AND COMPANY, AND
THE INDEPENDENT PETROLEUM ASSOCIATION OF AMERICA

(RELATING TO THE DERMAL CONTACT ISSUE)

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IN THE

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OCTOBER TERM, 1978

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INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
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JOINT MEMORANDUM IN OPPOSITION FOR RESPONDENTS

THE RUBBER MANUFACTURERS ASSOCIATION, INC., *ET AL.*,
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CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION,
E. I. DU PONT DE NEMOURS AND COMPANY, AND
THE INDEPENDENT PETROLEUM ASSOCIATION OF AMERICA

(RELATING TO THE DERMAL CONTACT ISSUE)

Respondents The Rubber Manufacturers Association, Inc., and six member companies,[1] the American Petroleum Institute, *et al.*,[2] Chemical Specialties Manufacturers Association, E.I. du Pont de Nemours and Company, and The Independent Petroleum Association of America oppose the issuance of a writ of certiorari to review the judgment of the United States Court of Appeals for the Fifth Circuit entered in this case on October 5, 1978.[3]

OPINION BELOW

The opinion of the court of appeals is reported at 581 F.2d 493. (App. 1a-33a.)[4] Judge Clark wrote the opinion for a panel of the court comprised of Judges Coleman, Clark and Tjoflat.

[1] The six companies are The Armstrong Rubber Company, The Firestone Tire & Rubber Company, The General Tire & Rubber Company, The B.F. Goodrich Company, The Goodyear Tire & Rubber Company, and Uniroyal, Inc.

[2] The petroleum industry respondents included in the group with the American Petroleum Institute are named in the concurrently-filed companion Joint Memorandum In Opposition, at 2 n.1.

[3] This memorandum focuses on the second question presented for review in No. 78-1036.

See the companion Joint Memorandum in Opposition for respondents' discussion in opposition to issuance of a writ of certiorari based upon the question posed in No. 78-911 and upon the first question presented in No. 78-1036. These similar questions focus upon the airborne exposure limit but bear upon each of the provisions in the benzene standard.

[4] "App." refers to a separately bound Appendix to the Petition in No. 78-911.

JURISDICTION

The judgment of the court of appeals (App. 254a-255a) was entered on October 5, 1978. Petitioner Secretary of Labor has delegated his responsibility for administering the Occupational Safety and Health Act of 1970, 29 U.S.C. § 651 *et seq.* (the "Act"), to the Assistant Secretary of Labor for Occupational Safety and Health ("Occupational Safety and Health Administration" or "OSHA"). The jurisdiction of this court is invoked under 28 U.S.C. § 1254(1).

QUESTION PRESENTED[5]

1. Whether OSHA, in incorporating in the benzene standard a ban on dermal contact with liquids containing even small or trace amounts of benzene, was entitled to rely solely on outdated and inconclusive data while failing to obtain readily available evidence based upon "research, demonstrations, [and] experiments" as required by 29 U.S.C. § 655(b)(5).

STATUTE AND REGULATION INVOLVED

1. The Occupational Safety and Health Act of 1970.

Section 2(b) of the Act, 29 U.S.C. § 651(b), provides in part:

> (b) The Congress declares it to be its purpose and policy, through the exercise of its powers to

[5] As noted *supra* at 2 n.3, OSHA has set forth two questions which it believes are presented by this case, and this response addresses only the second of those questions. Because OSHA's statement of the second question is inadequate, it has been restated.

regulate commerce among the several States and with foreign nations and to provide for the general welfare, to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources . . . .

Section 3(8) of the Act, 29 U.S.C. § 652(8), provides:

> (8) The term "occupational safety and health standard" means a standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment.

Section 6(b)(5) of the Act, 29 U.S.C. § 655(b)(5), provides:

> (5) The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and the performance desired.

Section 20(a)(1) of the Act, 29 U.S.C. § 669(a)(1), provides in part:

> (a)(1) The Secretary of Health, Education, and Welfare, after consultation with the Secretary [of Labor] and with other appropriate Federal departments or agencies, shall conduct (directly or by grants or contracts) research, experiments, and demonstrations relating to occupational safety and health . . . .

Section 20(c) of the Act, 29 U.S.C. § 669(c), provides:

> (c) The Secretary is authorized to enter into contracts, agreements, or other arrangements with appropriate public agencies or private organizations for the purpose of conducting studies relating to his responsibilities under this Act. In carrying out his responsibilities under this subsection, the Secretary shall cooperate with the Secretary of Health, Education, and Welfare in order to avoid any duplication of efforts under this section.

2. **Permanent Standard for Occupational Exposure to Benzene.** The benzene standard (App. 34a-66a) and the accompanying preambular statement (App. 67a-251a) as originally issued by OSHA are found at 43 *Fed. Reg.* 5917-5970. The amendment to the benzene

standard (App. 252a) and the accompanying preamble[6] were published at 43 *Fed. Reg.* 27,961-27,971.

STATEMENT OF THE CASE

This case presents questions concerning two separate and essentially unrelated provisions of OSHA's Permanent Standard for Occupational Exposure to Benzene (the "benzene standard"). The first of these provisions regulates airborne exposure to benzene and requires employers to assure that no employee is exposed to an airborne concentration of benzene in excess of 1 part benzene per million parts of air (1 ppm) as an 8-hour time-weighted average. The second of the provisions operates independently of the airborne exposure limit and bans dermal contact with benzene or substances containing even small amounts of benzene.[7] (29 C.F.R. § 1910.1028(c)(2); App. at 36a.)

Respondents Rubber Manufacturers Association and six individual rubber companies (collectively "rubber companies"), supported by and joined in this brief by other industry respondents,[8] are affected pri-

[6] The preamble to the amendment has not been reprinted as part of the Appendix to the Petition in No. 78-911.

[7] A related provision of the standard requires employees to wear protective clothing and equipment where dermal or eye contact may occur. 29 C.F.R. § 1910.1028(h); App. at 42a. As described more fully below, the extent of the ban on dermal contact has varied since the issuance of the permanent benzene standard. The standard as originally adopted by OSHA prohibited all dermal contact with any liquid containing any amount of benzene. In the first five months following adoption of the standard, OSHA twice modified the ban on dermal contact.

[8] See *supra* at 2 n.3.

marily by the second of the two major provisions of the benzene standard—the ban on dermal contact. Rubber companies manufacture tires and a range of other products[9] from natural and synthetic rubber. In doing so, they use petroleum solvents, cements and other materials which contain benzene in small or trace amounts (less than 1.0 percent). Rubber company production operations require dermal contact with these solvents, cements and other materials.[10]

The record evidence relating to the dermal contact provisions of the standard is largely independent of the record evidence bearing on the airborne portions. In carrying out its review, the court of appeals made a separate analysis of the record for each of these two key provisions. Accordingly, the statement of the case which follows discusses the procedural posture of OSHA's rulemaking and the record evidence insofar as they relate particularly to the dermal contact issue.[11]

[9] These other products include such diverse items as tubes, hoses, v-belts, conveyor belts, tennis balls, adhesives, cements, tennis shoes, shoe products, and health and hospital products. See, *e.g.*, Comment of Rubber Manufacturers Association (May 12, 1978), Amend. Ex. 46-59, at 3-4. (For an explanation of the form of citation to the original record, see *infra* n. 11.)

[10] *Id.*

[11] The original record has been transferred to this Court from the United States Court of Appeals for the Fifth Circuit. References in this memorandum to the record will be to the original record. Where available, accompanying citations to the Appendix to the Petition in No. 78-911 will also be supplied.

References in this memorandum to the transcript of the hearings held by OSHA in 1977 will be to "Tr." References to the other documentary portions of the rulemaking proceedings on the original standard will follow the form set out in OSHA's certification of the administrative record to the court of appeals.

The statement of the case especially as it concerns the airborne issues is set out in the other joint memorandum being filed concurrently by the same respondents.

A. The Original Benzene Standard

Benzene is a substance to which most of us in the United States are exposed every day. It is found throughout our society, *e.g.*, in ambient air and in minute quantities in water supplies throughout the country.[12] Notably, benzene is present in gasoline, especially unleaded gasoline, at levels ranging up to 2-3 percent. Benzene also is a useful building-block intermediate chemical in its own right. It is present in trace quantities in all petroleum-based products, including essentially all plastics, synthetic fibers, petroleum-based fuels, cleaning fluids, solvents, deter-

Hearings were also held by OSHA in May 1978 on a proposed amendment to the standard. See *infra* at 15-19. References to those subsequent hearings will be to "Amend. Tr." References to the documentary portions of the further administrative record will similarly follow the form used in OSHA's certification of this further record to the court of appeals, except that OSHA's designations will be preceded by "Amend." as in "Amend. Ex. 0-00."

[12] Indeed, OSHA itself found that "Benzene has been detected in foods such as roasted peanuts, soybeans, chicken, meat, codfish, tomatoes, pineapples, strawberries and cheddar cheese." OSHA, Final Environmental Impact Statement on a Standard for Occupational Exposure to Benzene (January 1978), Ex. 223, at 8-9. See also Amend. Tr. 129-130; Testimony of Dr. Herman Kraybill (National Cancer Institute), Ex. 84.B-18, App. A at 2-3, Tr. 1176, 1192-1194; Testimony of Edward Baier (National Institute for Occupational Safety and Health), Ex. 84.A at 7, Tr. 749-750, 1131.

gents, pesticides, and a vast range of other chemical products.

On May 3, 1977, OSHA issued an Emergency Temporary Standard ("ETS") for Occupational Exposure to Benzene. (42 *Fed. Reg.* 22,515.) The ETS exempted from its coverage mixtures containing 1.0 percent benzene or less. Respecting dermal contact, the effect of that exemption was to permit employees to have dermal contact with mixtures containing 1.0 percent benzene or less.[13]

Thereafter on May 27, 1977, OSHA issued a Notice of Proposed Rulemaking for a permanent standard for benzene. (42 *Fed. Reg.* 27,451.) The proposed standard, like the ETS, contained a volume percentage exclusion, exempting from the standard's coverage work operations where "the only exposure to benzene is from liquid mixtures containing 1% (0.1% after one year from the effective date of this standard) or less of benzene by volume, or the vapors released from these liquids." (*Id.* at 27,460.) The preamble to OSHA's proposed permanent standard identified a "major" issue in the rulemaking proceeding to be "whether the final standard should exempt certain specified operations from its coverage." (*Id.* at 27,452.) On this issue OSHA proposed:

> [A] step-down procedure exempting those workplaces in which employee exposure to benzene occurs only from liquids containing benzene of 1% or less with a reduction of that percentage to 0.1% benzene after 1 year. (*Id.* at 27,454.)

[13] As noted in OSHA's Petition at 4, the ETS was challenged in judicial review proceedings, stayed, and never brought into effect.

Comments submitted by the Rubber Manufacturers Association and individual rubber companies protested the proposal to lower the liquid volume exclusion from 1.0 percent to 0.1 percent a year after issuance of the standard. Those comments questioned the availability to rubber companies of solvents containing only 0.1 percent of benzene.[14] The Rubber Manufacturers Association also offered a proposed definition of "liquid benzene" that would have avoided the problems now presented by the dermal contact sections.[15] OSHA's proposed "step-down" procedure underscored its focus upon a percentage exclusion, however, and parties submitting comments on the proposed standard understandably shared that focus. Submitted comments generally assumed that some percentage exclusion, not lower than 0.1 percent, would be adopted in the final regulation.[16]

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[14] B. F. Goodrich Comments (June 27, 1977), Ex - ; Rubber Manufacturers Association Comments (June 27, 1977), Ex. 6-59, at 1, 3; Firestone Comments (June 27, 1977), Ex. 6-48.

[15] Rubber Manufacturers Association Comments (June 27, 1977), Ex. 6-59, at 1, 3.

[16] Statement of Tyler (SOHIO), Tr. at 1815-1818; Rubber Manufacturers Association Comments (June 27, 1977), Ex. 6-59; Firestone Comments (June 27, 1977), Ex. 6-48; Du Pont Comments (June 27, 1977), Ex. 6-46.

The reasonableness of this assumption as to the intended scope of the standard is confirmed by OSHA's own actions during its informal hearings on the rulemaking proposal. For example, OSHA's economic consultant, Arthur D. Little, Inc., was explicitly directed by OSHA to carry out a study of the standard's feasibility on the assumption that the standard would include the 1.0 percent exclusion. Tr. at 507-509. Because OSHA had directed its own consultant to ignore small or trace levels of benzene in mixtures, there was no reason to believe that OSHA was even interested in mixtures containing amounts of benzene below the proposed exclusion level.

During OSHA's informal hearing on the proposed benzene standard, limited evidence was introduced on the dermal contact issue. In proposing the standard, OSHA had candidly admitted that "studies indicate benzene is not readily absorbed through intact skin." (42 *Fed. Reg.* at 27,470.) No significant contrary evidence regarding skin absorption was presented during the rulemaking proceeding. Dr. Howard Maibach,[17] the only witness participating in the rulemaking who reviewed in detail the state of scientific knowledge regarding skin absorption of benzene, concluded that "the overwhelming majority of the observations suggest that benzene does not penetrate the skin."[18] (Tr. at 2465.)

During the rulemaking proceeding, Dr. Maibach repeatedly testified that modern analytic techniques can produce conclusive answers regarding whether benzene is absorbed through skin and the rate of any absorption; whether absorption is affected by multiple exposures; and whether any absorption is harmless or less harmful than inhalation of benzene. (Tr. at 2465-2468.) The necessary tests could have been completed in six to twelve weeks. (Tr. at 2487.)

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[17] Professor of Dermatology, University of California Medical Center.

[18] The single reference in the record suggesting that benzene can be absorbed through the skin was made by Dr. Douglas Smith of the National Institute for Occupational Safety and Health. Without discussing the relevant scientific literature, citing any direct data, or in any other manner suggesting the basis for his opinion, Dr. Smith remarked:

> Apparently it [benzene] is not absorbed through the skin at the same rate as toluene and xylene but it nonetheless can be absorbed. (Tr. at 860.)

Nearly six months after the close of that hearing OSHA published the permanent benzene standard. In contrast to both the ETS and the proposed standard, the permanent standard provided no exclusion whatsoever for mixtures containing trace amounts of benzene. The permanent standard banned all dermal contact with liquid mixtures containing any amount of benzene (29 C.F.R. § 1910.1028(c)(2)),[19] and required employees to wear protective clothing and equipment where dermal exposure might occur (29 C.F.R. § 1910.1028(h)). It also required employers to affix "Cancer Hazard" labels on all containers of all products containing any amount of benzene (29 C.F.R. § 1910.1028(k)).

In announcing the permanent standard, OSHA offered no explanation for its last-minute and unexpected elimination of the exclusion for liquid mixtures with 1.0 percent or less benzene. OSHA imposed the draconian prohibition against dermal contact even though in the preamble announcing the permanent

[19] As noted *supra* at 8 n.12, benzene is present in minute quantities in water supplies throughout the country, as well as in everyday foods and elsewhere throughout our society. Consequently, as initially promulgated OSHA's standard would have produced absurd results. It would have imposed a ban on drinking water in workplaces in the United States and would have required that all workplace drinking fountains bear a "readily visible and legible" label stating: "CAUTION - CONTAINS BENZENE - CANCER HAZARD". 29 C.F.R. § 1910.1028(b), (c)(2), and (k)(2)-(4), as originally issued, 43 *Fed. Reg.* at 5963-5966; App. 34a-48a. See also the opinion of the court of appeals, 581 F.2d at 500; App. 12a. Solid materials would also have been affected. For example, the same label would have been required to be affixed to all cans of tennis balls made in the United States, but not to cans of tennis balls manufactured abroad.

standard, it acknowledged that "[i]nhalation is the primary route of entry of benzene in man." (43 *Fed. Reg.* at 5920; App. 78a.) OSHA further conceded that it did not know whether benzene is absorbed through intact skin:

> The record evidence on the effect of liquid benzene on the eyes or the skin is extremely limited. No scientific data as to the effects of benzene on the eyes was presented during the rulemaking proceeding. The few studies of skin effects on animals and humans are not definitive as to the extent of benzene that is absorbed through the intact skin or as to the comparative rate of absorption through damaged skin. (*Id.* at 5948-5949; App. 193a (citations omitted) .)[20]

Rubber companies filed a request with OSHA for a stay of the dermal contact provisions and certain other sections of the standard.[21] That request focused particularly on the fact that it was not feasible for rubber companies to continue their manufacturing operations in compliance with the ban on dermal contact. Manufacturing operations for tires, tennis balls, v-belts, conveyor belts, hoses and other products nec-

[20] OSHA's Petition incorrectly suggests that OSHA banned dermal contact only with liquids containing more than 0.5 percent benzene. Compare OSHA's Petition at 7 with *id.* at 5 n.4. To the contrary, on the basis of this limited "evidence", OSHA initially imposed a total ban on dermal contact with liquids containing *any* amount of benzene.

[21] Other industry respondents filed motions with OSHA for a stay of the effectiveness of the entire standard.

essarily involve dermal contact with solvents containing small amounts of benzene (less than 1.0 percent).[22]

The manufacture of tires, for example, involves the use of petroleum solvents as tackifying agents essential to the tire building process. (Amend. Tr. 87-89, 160-167, 185-186.) Layers of materials ("plies") swabbed with solvent are manually built up to construct tires. (*Id.*) To achieve the precision of attachment and adhesion critical for tire uniformity and compliance with government standards, full use and dexterity of the workers' hands is required. (*Id.*) Skintight, impervious gloves cannot be used; they would dissolve or become tacky upon contact with petroleum solvents and actually lead to greater hazards and exposure. (Amend. Tr. 78, 89, 133.) Hand creams or "barrier creams" also are not a feasible option to prevent dermal contact with petroleum solvents. (Amend. Tr. 133, 168-169.)

There are no suitable substitutes in tire building and other rubber company operations for petroleum solvents which contain small amounts of benzene as a contaminant. (Amend. Tr. 115-116.) Despite repeated requests by rubber companies, it is not possible to obtain from suppliers solvents which do not contain trace amounts of benzene. (Amend. Tr. 87, 153, 168, 186-187, 208-209, 213.) While the benzene content of such solvents has declined in recent years, it remains well above 0.1 percent and in some instances exceeds 0.7-0.8 percent. (Amend. Tr. 131, 151-153, 175-178,

[22] See Request for Stay on Behalf of Rubber Companies (March 3, 1978), Amend. Ex. 27-III-E-1 and E-2; Rubber Manufacturers Association Comments dated May 12, 1978, Amend. Ex. 46-59, at 3-9; Amend. Tr. 78-82, 87-89, 132-133, 160-167, 212.

196-197.) Very substantial quantities of solvents, exceeding 110 million gallons annually, are purchased by rubber companies throughout the United States from a number of suppliers. Moreover, the benzene content of solvents varies among suppliers, among different plants of the same supplier, and even among different shipments from the same plant of the same supplier. (Amend. Tr. 117-118, 175-178, 200-201, 207-209.)

In response to the various requests for stay, on March 8, 1978 OSHA informed rubber companies and other industry respondents that it would grant a stay of the standard as to "work operations where the sole exposure to benzene is from mixtures containing 0.1 percent or less benzene." (OSHA, Statement of March 8, 1978, ¶2.)

B. The Amendment To The Standard

Thereafter on March 28, 1978, OSHA published a notice of its limited stay of the standard[23] and of a rulemaking proceeding to amend the standard. (43 *Fed. Reg.* 12,890-12,891.)[24] That notice proposed an

[23] The entire benzene standard had previously been stayed by the court of appeals.

[24] OSHA further modified the scope of the standard by means of a "correction" document published March 31, 1978. 43 *Fed. Reg.* 13,561-13,563. Among other changes, OSHA "corrected" the preamble to the standard so as to exclude from the standard solids containing benzene (other than pure solid benzene, which generally exists only in scientific laboratories). One effect of this "correction" was to exclude cans of tennis balls and boxes of tennis shoes from the requirement that they be labeled as a "CANCER HAZARD". See *supra*, at 12 n.19.

amendment to exclude from the standard liquid mixtures containing 0.1 percent or less of benzene. The announcement sought to limit the points at issue to nine specific questions, and interested persons were instructed to address the proposed percentage exclusion only as it related to "airborne concentrations" of benzene. (*Id.* at 12,891.) Notwithstanding OSHA's lack of evidence as to whether dermal contact with liquid mixtures containing small amounts of benzene constituted a health hazard, OSHA sought no evidence on that issue.

Moreover, OSHA refused to consider such evidence in connection with the rulemaking even after the rubber companies expressly warranted to the Agency that Dr. Maibach was conducting a study of issues relating to dermal exposure to benzene. In short, OSHA actually rejected the rubber companies' proffer of such highly relevant, and even crucial, evidence.

During the new rulemaking proceeding, the rubber companies informed OSHA explicitly that Dr. Maibach had been commissioned to conduct the absorption test. (Amend. Tr. 70.) Dr. Maibach's own description of his testing program was received into evidence at the hearing. (Amend. Tr. 71-73.)[25] Nevertheless, Grover Wrenn, OSHA's Director of Health Standards Programs, flatly stated at the hearing that OSHA would not await the results of such a study even though these results could be made available to it within 180 days. (Amend. Tr. 20.)[26] Mr. Wrenn further

[25] Dr. Maibach was unable to appear in person because of his teaching schedule. Amend. Tr. 71.

[26] OSHA's Petition states that "it is surprising that industry parties, with so much money at stake, have not engaged physicians to perform the experiment and furnish the results to the Secretary." OSHA's Petition at 20 n.11. That statement is incorrect. As stated in the text, OSHA was informed of Dr. Maibach's study at the hearing on the proposed amendment to the standard. Moreover, the opinion of the court below specifically refers to Dr. Maibach's study. 581 F.2d at 508 n.27; App. 27a n.27.

Dr. Maibach has now in fact completed his fundamental study of the absorption of benzene with rhesus monkeys. A report of Dr. Maibach's study was submitted by rubber companies to OSHA on January 22, 1979. It is reprinted *infra*, as Appendix 1 to this Joint Memorandum. In important part, Dr. Maibach's study found that only minute amounts of pure benzene or benzene contained in rubber solvents were absorbed through the skin. Dr. Maibach's report states that in a topical application of rubber solvent containing a small amount of benzene, the "actual penetration was 0.0805 ± 0.0119% of the benzene portion (0.36%) of the applied dose, or 0.00029% benzene in relationship to the solvent applied." *Infra* Appendix 1 at 9a.

testified that OSHA did not have any independent plans to obtain data to determine whether a hazard existed from dermal exposure to mixtures containing small amounts of benzene. (Amend. Tr. 18.)[27]

In late afternoon on the day before oral argument in the court of appeals, OSHA announced the amendments to its benzene standard. (581 F.2d at 496 n.4; App. 2a n.4.) OSHA exempted liquid mixtures containing 0.5 percent or less benzene from the provisions of the standard for three years, and thereafter mix-

[27] During the rulemaking proceeding rubber companies strongly urged OSHA to provide in the standard for an "action level" that would permit dermal contact with liquids containing small amounts of benzene, similar in concept to the "action level" now in the standard for airborne exposures to low levels of benzene. Amend. Tr. 67-68, 76, 95, 98-99, 132-134, 136-137, 159, 170, 188-191, 212-215. This suggested solution was similarly ignored by OSHA. See, *e.g.*, Testimony of Mr. Wrenn, Amend. Tr. 62-63.

tures containing 0.1 percent or less benzene.[28] In doing so, OSHA recognized that the dermal contact provisions of the benzene standard posed a "real problem"[29] for rubber companies:

> [W]ith respect to dermal contact, avoidance of skin exposure is feasible for workers in most industrial sectors simply by the use of suitable protective clothing, such as impermeable gloves. *OSHA recognizes that in tire-building, the record evidence shows that at present there are no suitable methods available to prevent skin contact with solvents containing a small amount of benzene.* (43 *Fed. Reg.* at 27,968 (emphasis added).)

OSHA nonetheless chose not to modify the dermal contact provisions, but rather to rely on an across-the-board percentage exclusion providing a modicum of temporary relief for three years.[30] For the longer term, OSHA speculated as to the possibility of increased production of solvents containing less than 0.1 percent benzene and other unspecified technolog-

[28] OSHA also exempted certain previously-packaged mixtures from the standard's labeling provisions.

[29] OSHA's Supplemental Memorandum in Opposition to Stay (April 12, 1978), at 67.

[30] Rubber companies can in most cases obtain solvents at or less than the 0.5 percent level for use in their Eastern, Southern and Midwestern tire and other manufacturing plants. Even for these plants, the companies often are close to or at the 0.5 percent level without any margin for deviation. Amend. Tr. 117, 131, 166-168. For West Coast plants, however, the 0.5 percent level could not be met, since in some instances suppliers could only meet a limit of 0.7 percent benzene in suitable solvents. Amend. Tr. 176.

ical developments, without citing any factual basis and in the face of substantial evidence to the contrary. (43 *Fed. Reg.* at 27,970.) OSHA cited no new health evidence in support of the amendment.

C. Judicial Proceedings And The Decision Below

On March 10, 1978, the American Petroleum Institute, *et al.*, and the Rubber Manufacturers Association, *et al.*, filed motions for stay of the benzene standard with the court of appeals.[31] They were soon joined by other producers and users of benzene who also sought a stay. On March 13, 1978, argument was had before Judge Morgan of the court on the stay motions. Later that day, Judge Morgan issued a temporary stay of the standard pending a hearing before a full panel of the court of appeals.

The issues concerning the stay were then fully briefed by the parties on an expedited basis. Numerous factual affidavits were submitted. A hearing on the stay was had on April 18, 1978 before a three-judge panel of the court of appeals. After the hearing, the court issued an order continuing in effect the temporary stay issued on March 13, 1978, "pending disposition of the petitions for review filed in these cases." In the same order the court of appeals established an expedited schedule for briefing the cases and it provided for accelerated oral argument.

[31] Various parties filed petitions for review of the benzene standard which were considered on a consolidated basis by the court of appeals. 581 F.2d at 4°5 n.1; App. 1a n.1.

Argument to the court of appeals in the consolidated cases was had on June 22, 1978. Since the amendment to the standard had been issued literally on the eve of oral argument, at the close of the argument the court of appeals directed the parties to file supplemental briefs, again on an expedited basis, directed to the effect of OSHA's amendments on the litigation. Thereafter on October 5, 1978, the court of appeals issued its decision granting the petitions for review of the benzene standard, setting aside the airborne permissible exposure limit and the dermal contact provisions, and also vacating the remaining provisions of the standard.

Specifically, the court of appeals vacated the dermal contact provisions on two separate and alternative grounds.[32] Rejecting OSHA's claim that its decision to prohibit dermal contact with liquid mixtures containing small amounts of benzene was supported by "substantial evidence",[33] the court stated that:

> OSHA's decision to regulate on the basis of dated, inconclusive data when modern experimental methods can quickly and efficiently provide reliable information contravenes the directive from Congress to promulgate standards on the basis of the "best available evidence," "research, demonstrations, experiments, and such other information as may be appropriate," and "the latest available scientific data in the field." 29 U.S.C.A. § 655(b)(5). This is not a case where there is testimony that additional research could be attempted, but might not shed new light on a subject. (581 F.2d at 507; App. 26a-27a.)

[32] It did not reach the issue of feasibility of the dermal contact provision, the third asserted ground for setting the provisions aside. See *infra*, at 23.

[33] Petitioner incorrectly asserts that the court of appeals found OSHA's adoption of the dermal contact provisions to be supported by "substantial evidence". OSHA's Petition at 11, 20. To the contrary, the court, after reviewing the "dated, inconclusive data" relied upon by OSHA, stated that "OSHA's finding that dermal contact with benzene poses a cancer risk *could* pass muster" if that had been the only evidence in the record. 581 F.2d at 507; App. 25a (emphasis added). The court then considered Dr. Maibach's testimony describing available and reliable experimental techniques which could resolve within a relatively short

In reaching that conclusion, the court reviewed in detail not only the limited data considered by OSHA but also Dr. Maibach's "unrefuted testimony" as to the reliability and accuracy of straightforward experimental techniques relating to benzene absorption.[34] On the basis of that detailed factual review, the court held that:

> OSHA's choice to rely on old and inconclusive evidence that there is a possibility of absorption

term the issue of whether human skin absorbs benzene, and found that Dr. Maibach's "additional evidence remove[d] the support for OSHA's actions." *Id.*

Indeed, at a prior point in its opinion, where the court summed up its ruling on the dermal contact provisions, the court stated:

> The record therefore fails to support the finding that benzene is absorbed through the skin. Since entry to the body by dermal contact was not established, the record will not support a finding that the prohibition of all dermal contact with benzene . . . [is reasonably necessary]. 581 F.2d at 506; App. 23a-24a.

[34] The court also referred expressly to the fact that the new test results were "so readily available". 581 F.2d at 508; App. 27a.

> of benzene through the skin which might cause cancer is in clear disregard of the Congressional directive as to the kinds of evidence OSHA is required to consider. Therefore, the provision of the standard prohibiting dermal contact with liquid benzene cannot stand on the present record. (581 F.2d at 508; App. 27a.)

The court of appeals also vacated the dermal contact provision on the ground that it was not "reasonably necessary" as required by Section 3(8) of the Act, 29 U.S.C. § 652(8). OSHA had sought in the court of appeals to justify the dermal contact prohibition as an adjunct to the permissible airborne exposure limit and on the basis of a concern for dermatitis. Both contentions were rejected. The court's analysis of the record led it to conclude that the argument on dermatitis "appear[ed] to be a post hoc rationalization for the dermal contact prohibition since it was not a significant part of OSHA's reasoning process that led to [that] provision." (581 F.2d at 505; App. 22a.) Because review of the standard "must be of the reasoning process of the agency at the time it promulgated the standard based on the record before it" (581 F.2d at 506; App. 23a),[35] the court refused to give weight to the newly proffered argument on dermatitis. And

[35] As authority for this principle, the court cited *Dry Color Mfrs.' Ass'n, Inc.* v. *Department of Labor*, 486 F.2d 98, 104 n.8 (3d Cir. 1973), which in turn cites and relies on this Court's decisions in *Citizens To Preserve Overton Park* v. *Volpe*, 401 U.S. 402, 419 (1971); *N.L.R.B.* v. *Metropolitan Life Ins. Co.*, 380 U.S. 438, 443-444 (1965); and *Burlington Truck Lines* v. *United States*, 371 U.S. 156, 168-169 (1962), along with *United States* v. *Allegheny-Ludlum Steel*, 406 U.S. 742, 756-757 (1972).

noting that the record did not support OSHA's finding that benzene is absorbed through the skin, the court determined that:

> [T]he record will not support a finding that the prohibition of all dermal contact with benzene will result in quantifiable benefits in terms of a reduced risk of leukemia justifying the costs of the provision. Thus reasonable necessity is lacking here too. (*Id.*; App. 23a-24a.)

The court of appeals did not reach the issue of whether OSHA's ban on dermal contact was "feasible" within the meaning of Section 6(b)(5) of the Act, 29 U.S.C. § 655(b)(5), stating that "the amendment to the standard on June 21, 1978, significantly affect[ed] the feasibility issue . . . ." (*Id.*; App. 23a.)

REASONS FOR DENYING THE WRIT

I. The Evidentiary Question Stated By OSHA Is Purely Hypothetical; The Facts And Record Demonstrate That There Is No Evidentiary Issue In This Case Worthy Of This Court's Consideration

The second question OSHA seeks to pose is not presented by the case. As OSHA characterizes the decision of the court of appeals and the record, the court first concluded that the dermal contact provisions of the benzene standard were supported by substantial evidence in the record. (OSHA's Petition at 2, 11, 20.) OSHA then asserts that the court of appeals set aside the dermal contact provisions "because of the possibility that future scientific studies will provide better evidence concerning the need for the

standard." (*Id.* at 2.) Because OSHA's factual premises are not correct, this Court is faced not with the question OSHA would like to present but rather with a very different issue.

The court of appeals actually rejected as insubstantial the "old, inconclusive evidence" which formed the predicate for OSHA's decision to regulate dermal contact as it did. (581 F.2d at 508; App. 27a; see also 581 F.2d at 506; App. 24a.)[36] The court did so in light of *all* the evidence in the record. This included the old data of inconclusive nature and manifest unreliability, plus Dr. Maibach's testimony that a test using radioactive benzene could rapidly and conclusively establish whether, or to what extent, benzene is absorbed through human skin. The court of appeals knew that Dr. Maibach was in fact then carrying forward such a study. (581 F.2d at 508 n.27; App. 27a n.27.)[37] And

[36] Only one study suggested that benzene was absorbed through human skin. The description of that study, set out in the decision of the court of appeals, shows its inconclusive and questionable nature:

> Between 1946 and 1961, experiments were conducted to determine whether human skin absorbed benzene. Although the first several of these studies conducted in the late 1940's and mid-1950's had negative results, one study published in 1961 found that some absorption had occurred and concluded that "the absorption of benzene throughout the skin must not be neglected." The record reveals problems in the interpretation of all of these studies, however. In particular, the 1961 study reporting positive results used a technique compressing benzene-soaked cotton against the skin with a glass plate for prolonged periods, that is recognized today as an efficient way to drive molecules into the skin. 581 F.2d at 506; App. 24a.

[37] During the May 1978 hearings on the proposed amendment to the standard, OSHA had been supplied with the test protocol being used by Dr. Maibach, and the approximate schedule for the study. Amend. Tr. 70-73.

the ruling of the court of appeals was also based on its determination, reflecting the record, that the "factual information [being provided by Dr. Maibach's study] is so readily available." (581 F.2d at 508; App. 27a.)[38]

Given the actual state of the record, which is very far from what OSHA would have this Court believe, the court of appeals reached the eminently sensible result. Moreover, OSHA cannot argue here, as it does respecting the first question presented by its Petition, that the statute bars the Agency from itself being sensible.[39] Section 6(b)(5) of the Act, 29 U.S.C. § 655(b)(5), directs OSHA in promulgating standards dealing with toxic materials to consider the "best available evidence", to develop standards "based upon research, demonstrations, experiments, and such other information as may be appropriate," and to consider "the latest available scientific data in the field." The decision of the court of appeals faithfully follows and implements these statutory provisions.

Especial note should be taken that the factual representations in OSHA's Petition at 20 and in footnote

[38] The fundamental information, involving absorption tests of radioactive benzene with rhesus monkeys, is now actually in OSHA's hands. See *supra*, at 16 n.26, and *infra* Appendix 1.

[39] As to the first question, pertaining to the "reasonable necessity" for OSHA's standard, OSHA argues that Section 6(b)(5) of the Act "prohibits" the Agency from evaluating cost-benefit considerations or making a risk analysis. OSHA's Petition at 17 n.10. Neither Section 3(8) nor Section 6(b)(5) of the Act impose such a restriction. See the companion Joint Memorandum In Opposition, filed concurrently with this memorandum.

11 (bearing on Dr. Maibach's study) are inexplicable, in light of the record.[40]

This is a record-dependent case, as one would expect, because the second question presented by OSHA's Petition pertains to the evidentiary portions of the standard-setting provisions of the Act. This Court should analyze the record before deciding whether or not to grant OSHA's Petition. Such analysis will show that the question OSHA has stated is not actually presented by the facts. On the facts, Dr. Maibach's test protocol is not a tentative or experimental procedure which possibly could provide evidence bearing on a crucial point. Rather, the experimental methods involving radioactively-tagged benzene are simple, direct and produce conclusive results. They can "so readily" provide, and now actually have provided, fundamental evidence on the absorption point. In the circumstances, this Court should deny the Petition.

II. OSHA's Own Failure To Provide Adequate Notice Of Issues In The Rulemaking Inhibited Orderly Development Of The Record

As described in the statement of the case, *supra*, at 9-10, OSHA failed during the proceedings on the proposed standard to give adequate notice that it was considering covering by the standard any material with any benzene content whatsoever. OSHA's ETS

[40] This Court will have the full record available to it during its consideration of the petitions for a writ of certiorari.

and proposed standard both had a "percentage exclusion", exempting from coverage materials with less than a specified percentage benzene content. (See *supra*, at 9.) When OSHA issued a standard covering any material with any benzene content, its action came as a total surprise, at least to respondents. In the absence of any express notice, it was not reasonable for them or for anybody else to have conceived that even OSHA would establish a benzene standard with the effect, among other things, of banning skin contact with tapwater in workplaces.[41]

Because the rubber companies had relied on the proposed percentage exclusion as limiting their concern with the proposed standard (see *supra*, at 10), they had not then sought to have Dr. Maibach or anyone else carry out a skin-absorption study using radioactive benzene. When the final standard issued without any percentage exclusion, they promptly sought both administrative relief and a judicial stay. (See 581 F.2d at 500 n.19; App. 12a n.19.) They also began work with Dr. Maibach to carry out an absorption study. OSHA subsequently granted a stay as to work operations involving mixtures of 0.1 percent or less benzene, and initiated a rulemaking proceeding to determine whether this or another percentage ex-

[41] As noted, benzene is a widely-occurring, natural organic material. See *supra*, at 8-9. The presence of benzene in potable water supplies in the United States has been reported by, among others, the National Academy of Sciences. And as the court of appeals observed, "the permanent standard prohibited all dermal contact with liquids containing any amount of benzene and it imposed the labeling requirements on all such liquids." 581 F.2d at 500; App. 12a.

clusion should be made a permanent part of the standard. (43 *Fed. Reg.* 12,890-12,891.) It was during these subsequent proceedings on the proposed amendment that the rubber companies presented detailed evidence relating to the infeasibility of tire manufacturing and other operations. As described *supra* at 15-17, in the subsequent proceedings the rubber companies also presented Dr. Maibach's protocol and schedule for his absorption tests using radioactive benzene.

The subsequent proceedings on the amendment accordingly were, and are, very important to the rubber companies. OSHA's decisions on the percentage-exclusion issue provide the impetus for and the emphasis on Dr. Maibach's work. The court of appeals pointedly observed "the major effect of the amendment is on the arguments regarding the feasibility of the dermal contact and labeling provisions." (581 F.2d at 501; App. 12a.) Most importantly here, the development of the factual record in this case can only be explained in light of OSHA's actions on the percentage-exclusion issue. This point was strongly made in the court of appeals, and in reaching its decision the court took cognizance of the problem caused by the lack of notice. (*Id.*)[42]

[42] One of the consequences is that the court of appeals took note of, but did not decide, the claims of the rubber companies that the dermal contact provisions were infeasible notwithstanding the amendment. Thus also, even if this Court were to grant the petition for writ of certiorari as to both questions and render a decision on the merits in OSHA's favor, it would still be necessary to remand the case to the court of appeals for consideration of the rubber companies' feasibility claim.

OSHA's Petition is technically correct in stating that "No one has argued that [OSHA] prevented the parties from performing and submitting such a test [as Dr. Maibach's study]." (OSHA's Petition at 20.) Yet while OSHA did not "prevent" the parties from carrying out an absorption study, neither did it inform the parties that the percentage exclusion would be eliminated from the final standard, and that the ban on dermal contact and thus the question of absorption would be of such concern.[43]

In sum, OSHA's own actions and especially its failure to provide notice to affected parties have inhibited the orderly development of the record. This lack of notice has led directly to the circumstance that the fundamental Maibach study has only recently been completed, approximately eleven months after the original benzene standard was promulgated. More particularly, in part because notice was lacking, the question OSHA would pose to this Court on petition for writ of certiorari is not fairly presented by the facts. The writ should be denied.

On the merits, OSHA should not be allowed to force regulated parties to bear the results of its own derelictions in imposing regulations absent evidentiary support. The court of appeals correctly observed that in the circumstances OSHA itself had to shoulder the responsibility for coming forward with the absorption information:

> When such factual information is so readily available, 29 U.S.C. § *655(b) (5) requires OSHA to ac-*

[43] In its Petition, OSHA almost ignores the fact that a major amendment to its standard was made. *Compare* OSHA's Petition at 7, *with id.* at 5 n.4. It understandably would not care to emphasize the reasons why an amendment was deemed necessary.

quire that information before promulgating regulations which would require an established industry to change long-followed work processes that are not demonstrably unsafe. (581 F.2d at 508; App. 27a (emphasis added).)[44]

III. There Is No Conflict—The Evidentiary Issue Before The Court Of Appeals Was And Is A Matter Of First Impression

OSHA cites no conflict of decisions on the evidentiary issue. To respondents' knowledge there is none. The court of appeals dealt with the matter as one of first impression.

[44] This aspect of the case seems particularly troublesome because OSHA apparently considers that it has power in effect to force parties "to supply [it] with relevant evidence" (OSHA's Petition at 20 n.11), by threatening to act to regulate unless evidence is forthcoming. Respondents do not concede that OSHA has been given such power by Congress in Section 6(b) of the Act, 29 U.S.C. § 655(b).

OSHA itself can obtain technical data if it desires to do so. OSHA may request that the National Institute for Occupational Safety and Health carry out technical studies (see Section 20(a) of the Act, 29 U.S.C. § 669(a)), or OSHA may enter into contracts with private parties to have such studies carried out. See Section 20(c) of the Act, 29 U.S.C. § 669(c).

CONCLUSION

For the foregoing reasons, the petitions for a writ of certiorari should be denied.

Respectfully submitted,

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APPENDIX 1

PERCUTANEOUS PENETRATION OF BENZENE AND BENZENE CONTAINED IN SOLVENTS USED IN THE RUBBER INDUSTRY

by

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January 19, 1979

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APPENDIX G—CALCULATION OF PERMITTED AIRBORNE EXPOSURE TO BENZENE AT 1 PPM

APPENDIX H—

H-1: Feldmann, R.J. & Maibach, H.I., "Absorption of Some Organic Compounds Through the Skin in Man", *J. Invest. Derm.* 54:399-404, 1970.

H-2: Wester, R.C. & Maibach, H.I., "Rhesus Monkey as an Animal Model for Percutaneous Absorption", pp. 133-137, in Maibach, H.I. (ed.) *Animal Models in Dermatology*, Churchill Livingstone, Edinburgh, 1975.

H-3: Wester, R.C., Noonan, P.K. & Maibach, H.I., "Frequency of Application on Percutaneous Absorption of Hydrocortisone", *Arch. Dermatol.* 113:620-622, 1977.

H-4: Wester, R.C., Noonan, P.K. & Maibach, H.I., "Variations in Percutaneous Absorption of Testosterone in the Rhesus Monkey Due to Anatomic Site of Application and Frequency of Application", Draft Publication in Preparation.

I. INTRODUCTION

This report describes skin absorption of: 1) full strength benzene; and 2) benzene which is present in trace amounts in solvents used in the the rubber manufacturing industry. The purpose of the study was to determine the extent of benzene percutaneous penetration (if any) using full strength benzene and rubber solvent containing small amounts of benzene. The study was conducted as described in the detailed protocol (Appendix A).*

II. PROTOCOL

Purpose

To determine the extent of benzene percutaneous penetration (if any) and the kinetics thereof.

Method

The experimental details are those described by Feldmann, R.J. & Maibach, H.I., as published in "Absorption of Some Organic Compounds Through the Skin in Man", *J. Invest. Derm.* 54:399-404, 1970 (Appendix H-1).

Parenteral

C^{14} benzene will be injected parenterally into the rhesus monkey, at a dose less than 1 mg. Urine and feces will be collected for appropriate assay of C^{14} to ascertain the completeness of excretion (and the kinetics thereof). Should this demonstrate that benzene (and its metabolites) are largely excreted and not stored, the cutaneous experiments will be started.

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* Funding for the study was provided by certain member companies of the Rubber Manufacturers Association.

Cutaneous

C^{14} benzene will be applied to the forearm of the rhesus and urine and feces collected. The specimens are handled in a metabolic fashion with aliquots examined at least daily for kinetic analysis. The initial skin dose will be approximately 4 micrograms/cm^2.

Solvent

Similar experiments will be performed with the benzene content at a level believed comparable to that found in typical rubber solvents. In this instance the dose calculations include that of the solvent and benzene.

General

1. Animals are already trained to sit in metabolic chairs.
2. Animals are tended to several times daily by staff.
3. All radioactivity counting methods have been extensively used for similar experiments in man.
4. Computer programs for handling the data are operational.
5. Three animals will be utilized in each experiment.

III. RESULTS

A. Parenteral Administration of Benzene

Purpose

To determine the excretion of a parenteral dose of (C-14) benzene. This will be used in percutaneous penetration experiments, as a parenteral recovery control.

Procedure

The dose was given to three rhesus monkeys restrained in metabolic chairs in a carefully controlled environmental

room. The dose given was 0.785 microcuries dissolved in propylene glycol. The dose was injected in the thigh of the monkeys.

Urine samples were pooled at 4, 8, 12 and 24 hours, and then at 24-hour intervals for the remaining four days. Two mililiter aliquots of the urine samples were dissolved in triton-toluene-PPO cocktail and counted. The efficiency was determined using a (C-14) toluene internal standard of 1×10^6 dpm. Additional details are in the detailed protocol attached as Appendix A.

Results

The average excretion was 41.02 ± 9.41% of the injected dose with individual values of 47.04, 45.84 and 30.18%. The last value of 30.18% should be considered only approximate because of the loss of some of the urine in the first sample. The true excretion is most probably in the area of 46% of the injected dose. Analytical data reflecting these results is set forth in Appendix B. This parenteral excretion data is to be utilized in preparing the correction figure for topical experiments, i.e., to correct for incomplete urinary excretion. No significant counts were found in the feces.

B. Percutaneous Pentration of Benzene: Topical Exposure

Purpose

To determine the percutaneous penetration of benzene after a small quantity was placed on the skin and allowed to evaporate.

Procedure

Three healthy rhesus monkeys were isolated in metabolic chairs with a device to isolate one forearm. The monkeys were sedated with Ketamine[R] during the procedure, and their forearm hair was removed with a clipper.

The monkeys were transferred outside the building to minimize inhalation and to preserve the controlled atmosphere of the laboratory. Fifty microliters (43.95 mg) of benzene with an activity of 4.33 microcuries was applied to a 1 inch by 2 inch (12.9 cm^2) area and allowed to dry. The treated arm was kept isolated for four hours.

Urine samples were pooled at 6, 12 and 24 hours and then daily for the remainder of the experiment. The feces were removed and discarded daily. The urine was analyzed by direct scintillation counting in triton-toluene-PPO, and an internal standard was added for an efficiency determination of each sample.

Results

Based upon initial analyses, the amount of label recovered was 0.101, 0.051 and 0.113% of the applied dose with an average of 0.088 ± 0.033% in 120 hours. The excretion of a parenteral dose was 41.0% and using this correction factor the actual penetration would be 0.2153 ± 0.0805%. Data is set forth in Appendix C.

However, the urine's radioactivity was measured by direct counting in triton-toluene-PPO cocktail; this method has an inherent drawback impairing accuracy when the counts in a sample are close to background levels. The potassium concentration in the urine varies, and the potassium has a significant number of *beta* emitting isotopes.

A reanalysis was therefore performed using the chromic acid oxidation method. The samples were oxidized using chromic acid, and the $^{14}CO_2$ evolved was captured and counted by liquid scintillation. This is a more accurate method.

The excretion determined by this analysis are 0.0436%, 0.0500% and 0.118% of the applied benzene dose with an average of 0.0705% ± 0.0412%. Using the correction factor of 2.44 determined in the parenteral study of benzene, the actual penetration was 0.172 ± 0.100%. Data is set forth in Appendix D.

C. Percutaneous Penetration of Benzene: From a Rubber Solvent

Purpose

To determine the percutaneous penetration of carbon 14 benzene as a component of a rubber solvent containing 0.36% benzene. This solvent was supplied by the Rubber Manufacturers Association and its characteristics are described in Appendix E.

Procedure

Three rhesus monkeys were placed in metabolic chairs, and had their forearms shaved three days prior to the penetration experiment. A solvent mixture of the rubber solvent with 0.36% benzene containing 18.7 microcuries per 50 microliter dose was prepared. The 50 microliter dose was applied over an area of 2 in^2 (2 × 1 in.) and allowed to evaporate.

To prevent inhalation of the C-14 benzene the monkeys wore gas masks during the application and evaporation period. The application was done in the open air to preserve the controlled atmosphere of the facility they were housed in.

Urine was collected at 4, 8, 12 and 24 hours on the first day and than 24-hour intervals to 120 hours. The feces were removed and discarded daily.

The urine was analyzed using the wet ashing method; chromic acid was used to oxidize the organic components

in a five mililiter aliquot of urine and the $^{14}CO_2$ was captured in an organic base. The $^{14}CO_2$ was counted via scintillation counting in a toluene-PPO cocktail.

Results

The ^{14}C-benzene and metabolites detected in the urine were at 0.0274%, and 0.036% and 0.0353% of the applied dose with an average of 0.0330 ± 0.0049%. Using the parenteral correction factor of 2.44 the actual penetration was 0.0805 ± 0.0119% of the benzene portion (0.36%) of the applied dose, or 0.00029% benzene in relationship to the solvent applied. Data is set forth in Appendix F.

IV. CONCLUSIONS

Full strength C-14 benzene was injected into rhesus monkeys and its presence was identified quantitatively and kinetically through analysis of the urine and the feces (see section III-A). Radioactive benzene was applied to the forearm of the monkeys to quantitate absorption. Using the correction factor of 2.44 determined in the parenteral study, the actual penetration was 0.172 ± 0.100% of the 100% benzene administered (see section III-B). Carbon-14 benzene as a component of a rubber solvent containing 0.36% benzene was applied topically to the forearm of the monkeys. Using the parenteral correction factor of 2.44, the actual penetration was 0.0805 ± 0.0119% of the benzene portion (0.36%) of the applied dose, or 0.00029% benzene in relationship to the solvent applied (see section III-C). The 0.172% and 0.0805% penetration figures suggest that when similar amounts of benzene are presented in diluted and concentrated forms, proportionally less benzene may be absorbed in the diluted form.

The rhesus monkey was selected for these experiments because it has been shown to be a reasonable model for percutaneous absorption where relevance to man is

sought.[1] While percutaneous penetration is a complex process, it appears from data derived from research with compounds other than benzene that absorption in the rhesus monkey bears a marked similarity to absorption in man.

The above relates to single exposures. In accordance with my earlier understanding with the rubber companies sponsoring this project, we will proceed with experiments to determine the effect on percutaneous penetration of multi-dose exposures to benzene or to rubber solvents containing small amounts of benzene. We do not know whether these experiments will show increased penetration, as previous studies indicate that percutaneous penetration is not necessarily increased by multiple exposures.[2]

Further experiments are necessary in order to draw conclusions as to the comparative amount of benzene absorbed through the respiratory and dermal routes in the rubber manufacturing industry. However, this study makes possible a preliminary judgment as to comparative absorption in humans based upon certain assumptions stated below.

The maximum permissible airborne exposure for benzene in the permanent benzene standard of the Occupational Safety and Health Administration is 1 part per million (ppm). A computation provided by the Rubber Manufacturers Association (Appendix G) indicates a maximum permitted exposure of 28.8 mg benzene over an eight-hour period for a worker doing moderately heavy work.

[1] Wester, R.C. & Maibach, H.I., "Rhesus Monkey as an Animal Model for Percutaneous Absorption", pp. 133-137, in Maibach, H.I. (ed.) *Animal Models in Dermatology*, Churchill Livingstone, Edinburgh, 1975 (Appendix H-2).

[2] Wester, R.C., Noonan, P.K. & Maibach, H.I., "Frequency of Application on Percutaneous Absorption of Hydrocortisone", *Arch. Dermatol.* 113:620-622, 1977 (Appendix H-3); Wester, R.C., Noonan, P.K. & Maibach, H.I., "Variations in Percutaneous Absorption of Testosterone in the Rhesus Monkey Due to Anatomic Site of Application and Frequency of Application", Draft Publication in Preparation (Appendix H-4).

The third phase of the study described in this report involved a single topical application of rubber solvent containing 0.36% benzene to the forearm of the rhesus monkey. The actual penetration was 0.0805 ± 0.0119% of the benzene portion (0.36%) of the applied dose, or 0.00029% benzene in relationship to the solvent applied. To make a preliminary judgment as to comparative absorption of benzene in man, it is necessary to assume that penetration through the portions of the hand exposed to rubber solvent containing 0.36% benzene is the same as penetration through the forearm of the monkey, that percutaneous penetration of the benzene in rubber solvent is not substantially increased by multiple exposures and that the extent of dermal contact does not exceed the equivalent of full palmar contact. If these assumptions are correct, a preliminary judgment is that the amount of benzene absorbed percutaneously from contact with rubber solvent containing 0.36% benzene is a small fraction of the amount of benzene permitted to be inhaled at 1 ppm. Further studies to document or disprove these assumptions are planned.

[The appendices to this report (appendices A-H) are not reproduced here. Those appendices are included in a copy of the report on file with the Clerk.]

Supreme Court, U. S.
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IN THE

Supreme Court of the United States

OCTOBER TERM, 1978

Nos. 78-911 and 78-1036

INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*,
Respondents.

RAY MARSHALL, SECRETARY OF LABOR,
Petitioner,

v.

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Respondents.

On Petitions for Writs of Certiorari to the United States Court of Appeals for the Fifth Circuit

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OPPOSITION OF RESPONDENT MANUFACTURING CHEMISTS ASSOCIATION

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OPPOSITION OF RESPONDENT MANUFACTURING CHEMISTS ASSOCIATION

Respondent Manufacturing Chemists Association ("MCA") submits this opposition to the Petitions for

Writs of Certiorari to review the judgment of the United States Court of Appeals for the Fifth Circuit in this case which have been filed by the Industrial Union Department, AFL-CIO ("IUD") and by the Solicitor General on behalf of the Secretary of Labor ("the Secretary") on December 7 and December 26, 1978, Nos. 78-911 and 78-1036, respectively.

OPINION BELOW AND JURISDICTION

The opinion below and the jurisdiction of this Court are set forth in the Petitions of the IUD and of the Secretary and will not be repeated here.

COUNTERSTATEMENT OF QUESTIONS PRESENTED

1. Whether a revised occupational health and safety standard for a toxic substance promulgated by the Secretary satisfies the statutory requirement that it be "reasonably necessary or appropriate to provide safe or healthful employment and places of employment" in the absence of substantial evidence in the record taken as a whole showing the extent to which employee safety or health will be enhanced thereby.

2. Whether the Secretary, in promulgating a revised occupational safety and health standard which is required to be based on the "best available evidence, . . . research, demonstrations, experiments" and "the latest available scientific data in the field" may rely on dated, inconclusive data when modern techniques are available to provide definitive answers.

STATUTE INVOLVED

The pertinent sections of the Occupational Safety and Health Act of 1970, 29 U.S.C. § 652(8), 655(b)(5) and 655(f), are set forth in the Petitions of IUD and of the Secretary and will not be repeated here.

COUNTERSTATEMENT OF THE CASE

1. The Occupational Safety and Health Act of 1970 ("the Act") authorizes the Secretary to promulgate mandatory occupational safety and health standards which are defined in 29 U.S.C. § 652(8) as meaning requirements that are "reasonably necessary or appropriate to provide safe or healthful employment and places of employment." In connection with occupational exposure to benzene,[1] three such standards have been promulgated.

In 1971, pursuant to 29 U.S.C. § 655(a), the Secretary[2] adopted the national consensus standard which imposed a permissible exposure limit ("PEL") of 10 parts of benzene per million parts of air (ppm) as an eight-hour time weighted average (TWA), an acceptable ceiling concentration of 25 ppm and an excursion level above the ceiling of a maximum of 50 ppm for not more than 10 minutes in any eight-hour work period. (App. 71a).[3] That standard is the standard presently in effect.

In 1974, the National Institute of Occupational Safety and Health (NIOSH) submitted a criteria document which noted a possible connection between benzene ex-

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[1] Benzene is "a ubiquitous hydrocarbon compound" (App. 5a). It is derived chiefly from the petroleum cracking process, although a small amount (6%) is produced as a by-product of coke ovens. In 1976, more than 11 billion pounds were produced, making benzene the second largest hydrocarbon product and the twelfth most widely produced chemical. It is a basic chemical feed stock and is used in the manufacture of other organic chemicals. It is also used in the printing, lithographic, stain remover, adhesive, rubber cement, rubber fabricating, paint, varnish, pesticides and detergent industries. It is a component of motor fuels including gasoline. (App. 69a-70a). Its presence in motor fuels acts as an octane booster.

[2] References herein to the Secretary include the Occupational Safety and Health Administration ("OSHA") which acted under the Secretary's responsibility.

[3] This and similar references are to the Appendix to the IUD Petition.

posure and leukemia, but recommended that the existing standard be essentially maintained. (App. 71a-72a). In 1976, NIOSH issued a revised criteria document concluding that benzene was a leukemogen and recommending an exposure level of 1 ppm or less. NIOSH also recommended the issuance of an emergency temporary standard (ETS) under 29 U.S.C. § 655(c). The Secretary declined to promulgate an ETS, but instead issued in January, 1977 voluntary guidelines recommending a 1 ppm 8-hour TWA level. (App. 73a).

On April 15, 1977, NIOSH transmitted to the Secretary the results of an epidemiological study (the so-called Infante Study) conducted at two plants in Ohio at which benzene had been used in the manufacture of a product known as Pliofilm. The period covered by the study was 1940 to and including 1949. NIOSH again recommended the issuance of an ETS. (App. 73a).

On May 3, 1977, the Secretary, relying on the Infante Study which purported to show an increased incidence of leukemia at exposures of "0 to 10 to 15 parts per million,"[4] issued an ETS reducing the exposure limit to 1 ppm. That ETS was stayed by the Fifth Circuit and never went into effect.

In February, 1978, after notice and hearing, OSHA promulgated its Permanent Standard for Occupational Exposure to Benzene, reducing the exposure level to 1 ppm for an 8-hour TWA and to a 5 ppm ceiling for any exposure for 15 minutes. In addition, the Permanent Standard prohibited dermal and eye exposure to liquid

[4] The Secretary later admitted that evidence at the hearing demonstrated "that there were area exposures during this study period exceeding these levels, at times reaching hundreds of parts per million," and that no "conclusions linking the excess leukemia risk . . . with any specific exposure level" could be derived from the Infante Study. (App. 105a).

mixtures containing benzene,[5] and required employers to conduct monitoring of exposure levels, to engage in detailed medical testing and surveillance of employees exposed to benzene, and to keep both exposure and medical records. The Permanent Standard was also stayed by the Fifth Circuit and has never become effective.

The Permanent Standard was accompanied by a lengthy preamble which recapitulated the scientific literature concerning the toxicity and alleged leukemogenicity of benzene. With regard to the leukemogenicity of benzene, the Secretary relied on a number of epidemiological studies for his conclusion that exposure to benzene had caused leukemia in workers. Each of those studies, however, either involved exposure levels considerably in excess of 100 ppm or exposure at unstated levels. For example, the study by Aksoy *et al.* of Turkish shoemakers showed exposure levels of 150-210 ppm. (App. 101a).[6] The Secretary was unable to produce any evidence of leukemia in workers exposed to levels of 10 ppm. He rejected, however, several industry studies which showed no excess incidence of leukemia at the current level of 10 ppm. And he concluded that since benzene was a leukemogen at some high exposure level, it

[5] As originally promulgated, the Permanent Standard prohibited dermal or eye contact with liquid mixtures containing *any amount of benzene*. After receipt of petitions for reconsideration asserting the impossibility of such a standard, the Secretary reopened the record and, on June 21, 1978 (the day before the argument in the Fifth Circuit), revised the standard so as to exempt liquid mixtures containing 0.5% benzene by liquid volume (0.1% after three years) and the labeling of such mixtures containing 5.0% or less benzene by liquid volume if such mixtures were in inventory before June 27, 1978. (App. 252a).

[6] As noted above, the NIOSH study of April 1977 (the Infante Study) upon which the Secretary relied in promulgating the ETS involved exposures of several hundred ppm rather than 10 ppm or less as the Secretary had erroneously believed.

was a leukemogen at any level and that any exposure must be considered to be attended by risk.[7]

Even though industry and the Council on Wage and Price Stability provided him with appropriate methods (App. 160a-161a) the Secretary declined to measure the extent of the benefit to employees which might be obtained by lowering the exposure level from 10 ppm to 1 ppm. Instead, he contented himself with the assertion that the number of cancers to be prevented "may be appreciable". (App. 160a).[8] This refusal to measure the benefits to be derived was based on the Secretary's interpretation of the Act which was to the effect that the Congress had "already arrived at a judgment concerning balancing cost and benefit" (App. 159a) and that OSHA was not permitted to "substitute cost benefit criteria for the legislatively determined directive of protecting all exposed employees against material impairment of health or bodily function." (App. 162a).

2. The court below set aside the Permanent Standard because it concluded that the Secretary had failed to show that the Standard met the statutory definition of section 3(8) of the Act as being "reasonably necessary or appropriate to provide safe or healthful employment and places of employment." In reaching that conclusion,

[7] As the court below noted (App. 13a, n.20), the Secretary reached this conclusion despite "the fact that all studies associating benzene and leukemia involve high benzene concentration levels, that a substantial body of the scientific community subscribes to the theory that safe threshold levels exist for exposure to carcinogens, and that empirical evidence shows that low-level exposure to benzene does not cause leukemia."

[8] The court below acknowledged that the Secretary's assumption that some benefit was likely "is not unsupported," but went on to emphasize that the "lack of substantial evidence of discernible benefits is highlighted when one considers that OSHA is unable to point to any empirical evidence documenting a leukemia risk at 10 ppm even though that has been the permissible exposure limit since 1971." (App. 18a).

the court rejected as overbroad the Secretary's interpretation of the Act. The court noted that Congress had not intended to give the Secretary "unbridled discretion to adopt standards designed to create absolutely risk-free work places regardless of cost." Instead, Congress imposed various "pragmatic limitations" on the Secretary's authority, including requirements that standards be "appropriate and necessary" and "feasible." (App. 15a-16a). Accordingly, the court read the Act as requiring the Secretary to make "rough but educated estimates of the extent of the benefits expected from reducing the permissible exposure level from 10 ppm to 1 ppm." (App. 21a). The court emphasized the limited and reasonable nature of its holding, stating that it was not requiring that the Secretary "wait until deaths occur" but only that OSHA should "have some factual basis for an estimate of expected benefits before it can determine that a one-half billion dollar standard is reasonably necessary." (App. 20a). The court concluded:

> "OSHA's failure to provide an estimate of expected benefits for reducing the permissible exposure limit, supported by substantial evidence, makes it impossible to assess the reasonableness of the relationship between expected costs and benefits. This failure means that the required support is lacking to show reasonable necessity for the standard promulgated. Consequently, the reduction of the permissible exposure limit from 10 ppm to 1 ppm and all other parts of the standard geared to the 1 ppm level must be set aside." (App. 21a-22a).

The court of appeals also set aside that part of the Standard dealing with dermal exposure. In doing so, it concluded that the requirement of the Act that standards be based on the "best available evidence" and "the latest available scientific data in the field" was not satisfied by dated and inconclusive data when modern techniques

are readily available to provide accurate information. (App. 26a-27a).[9]

REASONS FOR DENYING THE WRITS

Both the IUD and the Secretary contend that this Court should review the decision of the court of appeals because (1) it is in conflict with the decisions of other circuits which have dealt with OSHA standards; (2) it imposes on OSHA burdens which OSHA cannot carry; and (3) it has cast considerable doubt on OSHA's past and continuing administration of the Act. MCA respectfully disagrees with these contentions.

A. The Decision Below Is Not in Conflict with the Decisions of Other Circuits and Is Plainly Correct.

Petitioners assert that the decision below is in conflict with the decisions in *Industrial Union Department, AFL-CIO* v. *Hodgson*, 499 F.2d 467 (D.C. Cir. 1974); *Society of the Plastics Industry* v. *OSHA*, 509 F.2d 1301 (2d Cir. 1975), *cert. denied*, 421 U.S. 992 (1975); and *American Iron and Steel Institute* v. *OSHA*, 577 F.2d 825 (3d Cir. 1978) (petitions for *certiorari* pending in Nos. 78-918 and 78-919). MCA submits that the factual records and the issues decided in those cases are not the same and that the decisions are therefore not in conflict.

The court below applies the Act as a whole rather than in the selective, piecemeal fashion which the Secretary prefers. It did not restrict itself to the application of the section dealing with criteria for standards (29 U.S.C. § 655(b)(5)). Rather, it started with the basic question of the definition of an occupational safety and health standard which Congress put in Section 3(8) of the Act (29 U.S.C. § 652(8)). It concluded that:

[9] The question of dermal exposure is discussed in detail in the opposition filed by The Rubber Manufacturers Association, *et al.*

> "The Act imposes on OSHA the obligation to enact only standards that are reasonably necessary or appropriate to provide safe or healthful workplaces. If a standard does not fit in this definition, it is not a standard which OSHA is authorized to enact." (App. 15a).

From that elementary analytical starting point, the court went on to say that the reasonableness of a standard could only be tested by comparing the reasonableness of the relationship of the benefits which the standard would confer with the costs which the standard would impose. It found further support for that view from the "feasible" and other "pragmatic limitations" embodied in 29 U.S.C. § 655(b)(5). (App. 16a). The court also noted that the judicial review provision (29 U.S.C. § 655(f)) calls for upholding the Secretary if his determinations are "supported by substantial evidence in the record considered as a whole." (App. 4a). However, the court found no substantial evidence to support the Secretary's bare assertion that the benefits "may be appreciable." It therefore could not assess the reasonableness of the relationship between benefits and costs. Accordingly, it concluded that the Secretary had failed to show "reasonable necessity for the standard promulgated." (App. 21a).

While the court below is the first to have been specifically asked to consider the effect of the definition of a standard contained in 29 U.S.C. § 652(8) on the content of a particular standard, it is not the only circuit to have required that benefits be measured in relation to costs. In *Turner Company* v. *Secretary of Labor*, 561 F.2d 82 (1977), the Seventh Circuit set aside a decision of the Occupational Safety and Health Review Commission which involved enforcement of a standard dealing with noise. On the question of the feasibility of engineering and administration controls, the court adopted

the approach of the Commission in a companion case which had held:

> "[Controls] will not be required without regard to the costs which must be incurred and the benefits they will achieve. In determining whether controls are economically feasible, all the relevant cost and benefit factors must be weighed." (561 F.2d at 85).

The Seventh Circuit went on to conclude:

> "[T]he Commission must realistically consider the hazards presented by the excessive noise in Turner's Waterbury room and determine whether the health benefits to employees who are already equipped with personal protection equipment justify the $30,000 cost to Turner for engineering controls." (561 F.2d at 86).

The decisions of the District of Columbia, Second, and Third Circuits are not in conflict with the analysis of the Fifth and Seventh Circuits. They were based on different factual records. And the three courts of appeals involved were never presented with, and hence did not decide, the legal argument that some form of comparative cost-benefit measurement was necessary to the determination of the question whether the standards before them were reasonably necessary or appropriate to provide healthful workplaces.

Moreover, the court below was plainly correct in holding that some showing of benefit in relation to cost is necessary. The Secretary essentially so concedes when he states that the statute "does not preclude all consideration of cost-benefit assessments in the process of setting health standards for toxic substances." (Petition, n.10 at pp. 17-18). The distinction the Secretary then attempts to draw—that he is free to consider costs versus benefits in deciding whether to issue a new standard but not in deciding what the requirements of that standard should be—carries its own refutation. It is the

Secretary who advocates an impermissible reading of the statute—a reading which would require the lowest level of exposure which is technologically obtainable, without regard to the amount of benefits which that would obtain and without considering whether finite resources could be more sensibly employed elsewhere. Congress did not intend any such unbalanced approach when it enacted the statute for the purpose of assuring "*so far as possible* every working man and woman in the Nation safe and healthful working conditions" (29 U.S.C. § 651, emphasis added) and put on the Secretary the pragmatic limitations that standards be "reasonably necessary or appropriate" and "feasible." [10]

B. The Decision of the Court Below Does Not Place an Impossible Burden on the Secretary.

Petitioners are incorrect when they assert that the requirement that the Secretary engage in a cost-benefit analysis places an impossible burden on him. For example, the Secretary contends:

> "According to the court, the Secretary must demonstrate measurable benefits to be achieved by reductions in exposure to cancer-causing substances. If the relationship between exposure and disease is imperfectly known, so that benefits cannot be measured, then the Secretary cannot order a reduction in exposure. (Petition, pp. 12-13).

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[10] The case for denying review of the second question—which involves the dermal and eye contact provisions of the Standard—is even stronger. The petitions do not claim that there is any conflict on this point or that the decision on this point below prevents the Secretary from performing his functions. Also, the correctness of the holding below on this point is apparent from the discussion in the opinion (App. 22a-27a). The reasons why review of this point should be denied are elaborated in the opposition filed by respondents The Rubber Manufacturers Association, Inc., *et al.*

". . . the court, by deciding the case with the reasoning it employed, has crippled the Secretary's ability to deal with substances that cause cancer." (Petition, p. 16 n.9).

The IUD goes even further in asserting that the Secretary must wait until he can quantify the number of lives that would be saved (Petition, p. 2).

MCA respectfully submits that assertions of that kind are an exaggeration of what the court below requires of the Secretary. In fact, the court said as follows:

> "This does not mean that OSHA must wait until deaths occur as a result of exposure at levels below 10 ppm before it may validly promulgate a standard reducing the permissible exposure limit. *See Florida Peach Growers Association, Inc.* v. *United States Department of Labor*, 489 F.2d 120, 132 (5th Cir. 1974). Nevertheless, OSHA must have some factual basis for an estimate of expected benefits before it can determine that a one-half billion dollar standard is reasonably necessary. For example, when studies of the effects of human exposure to benzene at higher concentration levels in the past are sufficient to enable a dose-response curve to be charted that can reasonably be projected to the lower exposure levels, or when studies of the effects of animal exposure to benzene are sufficient to make projections of the risks involved with exposure at low levels, then OSHA will be able to make rough but educated estimates of the extent of benefits expected from reducing the permissible exposure level from 10 ppm to 1 ppm. Until such estimates are possible, OSHA does not have sufficient information to determine that a standard such as the one under review which it can only say might protect some worker from a leukemia risk is reasonably necessary." (App. 20a-21a) (footnotes omitted).[11]

[11] The above quotation serves to correct the incomplete quotation appearing in note 7 at page 10 of the Secretary's Petition.

Thus, the court of appeals is not asking the impossible of the Secretary. Nor is it instructing him to experiment with human life. It merely requires him to "make rough but educated estimates of the extent of benefits expected," based on some substantial evidence which may be derived, for example, from supportable dose-response curve projections from historical data or from animal experiments. The burden imposed on the Secretary is one of working—he is "to regulate on the basis of more knowledge and fewer assumptions than the record reflects" (App. 21a).

C. The Decision Will Not Interfere with the Administration of the Act.

As noted above, the Secretary contends that the decision of the court of appeals has "crippled [his] ability to deal with substances that cause cancer." That again is an exaggeration. Insofar as benzene is concerned, all the Secretary has to do is to reopen the proceedings and develop the rough but educated estimate of the benefits in order that they may be compared to the costs. Whether such a comparison would establish that the standard is reasonable or necessary may, of course, be a matter of controversy. But these kinds of estimates can be made. As the court below noted, the Secretary's own cost expert, Arthur D. Little and Company, testified that a cost-effectiveness analysis could be performed, and the Environmental Protection Agency had done a preliminary extrapolation (App. 19a and n.23).

Nor will the decision below necessarily interfere with other pending OSHA matters. OSHA now has before it a large proceeding dealing with the identification, classification and regulation of carcinogens. One of the issues in that proceeding is the matter of comparative risk assessment. And OSHA is a member of the Interagency Regulatory Liaison Group, one of whose purposes

is to consider methods of assessing the risks involved in exposure to toxic substances and of estimating the relative benefits of those substances. In short, OSHA and other agencies are already considering ways to perform exactly the type of estimating which the court below has required.[12]

D. Clarification of the Occupational Safety and Health Act Will Come from Other Courts of Appeal.

The Secretary contends that the decision below is important enough standing alone to warrant review. MCA respectfully disagrees. The interpretation placed upon the Act by the Fifth Circuit is the first to treat the definitional section and the criteria section as an interrelated whole. There are, however, pending before other courts of appeal petitions for review of three different OSHA standards. The cotton dust and lead standards are before the District of Columbia Circuit. And the inorganic arsenic standard is in the Ninth Circuit. Thus, those circuits that have not yet had the opportunity to consider the interpretation applied by the Fifth Circuit will be in a position to reach their own conclusions based on the individual records and issues before them. MCA submits that this Court should await further clarification of the law by the circuit courts of appeal, particularly since there is no compelling health need for action by this Court now.[13]

---

[12] The seemingly contradictory positions of OSHA should be noted. On the one hand, OSHA has stated that ". . . in setting an exposure limit . . . OSHA may not substitute cost benefit criteria for the legislatively determined directive of protecting all exposed employees against material impairment of health or bodily function." (App. 162a). On the other hand, it says that the Act "itself does not preclude all consideration of cost-benefit assessments in the process of setting health standards for toxic substances." (Secretary's Petition, n.10 at pp. 17-18).

[13] The petitions overstate the health considerations involved. Both the court below, and the District of Columbia Circuit (which briefly had the case on transfer), have found a stay of the Standard appropriate and petitioners have not sought to terminate the stay which is presently in effect. The assertion in the Secretary's petition (p. 14, n.9) that the Standard "governs the occupational exposure of some 629,000 workers to a known cause of cancer" needs to be put into perspective by pointing out that only 30,000 workers would be exposed above the 1 ppm level which the Standard would impose and they are protected by the 10 ppm level presently in effect. And if there is a need for going below the present 10 ppm level the Secretary, instead of seeking review here, should promptly develop the "rough but educated estimates of the extent of benefits expected from reducing the permissible exposure level from 10 ppm to 1 ppm" which the court below correctly held the statute requires.

CONCLUSION

For the reasons stated, the petitions for writs of certiorari filed by IUD and the Secretary should be denied.

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Nos. 78-911 and 78-1036

In The

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October Term, 1978

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On Petitions for a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

REPLY BRIEF OF INDUSTRIAL UNION DEPARTMENT, AFL-CIO IN SUPPORT OF PETITION FOR CERTIORARI

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I

The joint memorandum in opposition filed by the American Petroleum Institute, et al.[1] embraces only the result reached by the court below, and rejects the rest of the decision, at least so long as there is a chance to avoid review of that decision by this Court.

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[1] Joint Memorandum in Opposition for Respondents the American Petroleum Institute, et al., the Rubber Manufacturers Association, et al., the Chemical Specialties Manufacturers Association, E. I. duPont de Nemours & Co., and the Independent Petroleum Association of America, filed January 26, 1979. The parties filing the joint memorandum are hereinafter referred to as "API", and the memorandum as "API Opp."

The court below stated the basis of its decision as follows:

> OSHA's failure to provide an estimate of expected benefits for reducing the permissible exposure limit, supported by substantial evidence, makes it impossible to assess the reasonableness of the relationship between expected costs and benefits. This failure means that the required support is lacking to show reasonable necessity for the standard promulgated. Consequently, the reduction of the permissible exposure limit from 10 ppm to 1 ppm and all other parts of the standard geared to the 1 ppm level must be set aside. [App. 21a-22a]

That court was "not persuaded by OSHA's argument that this standard should be upheld since the lack of knowledge concerning the effects of exposure to benzene at low levels makes an estimate of benefits expected from reducing the permissible exposure level impossible." App. 19a. Instead, the court held that OSHA must stay its hand "[u]ntil such estimates are possible. . . ." App. 21a.

And, recognizing that its ruling conflicts with the decisions of other circuits upholding OSHA standards, the court did "not attempt to reconcile" its decision with the prior cases. App. 21a.

Because acknowledging what the Court below said and did leads inevitably to the conclusion that the question presented in the petition is substantial and that the courts of appeals are in conflict on the correct answer—conclusions that would defeat API's purpose—the API memorandum in opposition recites at length what it asserts is the evidence that "prompted" the Fifth Circuit's decision. (API Opp. 4, 5-15). Yet, the court of appeals neither relied upon nor even discussed any such supposed evidence. And for good reason: API's version of the "evidence" bears little resemblance to the testimony and exhibits which comprise the record of this case,[2] or to the findings the Secretary of Labor made on that record.

[2] The original record has been transferred to this Court from the court of appeals. References in this brief to the transcript of the rulemaking hearings conducted by the Secretary will be to "Tr." References to the exhibits submitted in the rulemaking proceedings will be to "Ex.", with the exhibits numbered in the form set out in the Secretary's certification of the record to the court of appeals.

Having made its own findings of fact, API then draws its own conclusion of law, contending that the court of appeals decided a "question never raised (and therefore never decided) in previous occupational health standard cases—namely, how [the Secretary] should regulate a substance showing minimal (if any) risks below the existing standard where there is a record basis for an imprecise, but useful, estimate of the benefits of reducing the PEL." API Opp. 19. But the Fifth Circuit's opinion makes it plain that the court did *not* rest its decision upon findings that benzene poses "minimal" risks below the level of the existing standard, or that a "record basis" exists by which the Secretary could perform the quantification of benefits required by the court's construction of the Act. Such findings were not even made, let alone relied upon, by the court below.[3]

[3] The Court expressly upheld the Secretary's determination that low levels of exposure to benzene pose a leukemia risk, and held only that the Secretary had not been able to adduce substantial evidence as to "the extent of" that risk. App. 18a-19a. While the court noted that a risk at levels of exposure approximating the PEL could not be documented by "empirical evidence", but rather had been inferred from studies involving higher levels of exposure (*id.*), the same was true in each of the prior cases which API strives to distinguish: *American Iron and Steel Institute ("AISI")* v. *OSHA*, 577 F.2d 825, 831-832 (3d Cir. 1978), *petitions for cert. pending*, Nos. 78-918, 78-919; *Society of the Plastics Industry* v. *OSHA*, 509 F.2d 1301, 1308 (2d Cir.), *cert. denied*, 421 U.S. 992 (1975); *Industrial Union Department* v. *Hodgson*, 499 F.2d 467, 475, 479 and n. 27 (D.C. Cir. 1974).

Nor did the court below hold that a "record basis" exists by which the Secretary could carry out the benefit quantification required by its decision. To the contrary, the court recognized that the Secretary "will be able" to make the estimates required by its ruling only when certain scientific studies, which have proved unsuccessful to date, become "sufficient." App. 20a-21a.

Consequently, API's lengthy recitation of the "evidence" which it claims would have supported such findings is entirely beside the point. But because API's rewriting of the record could mislead if left unanswered, we note the most obvious errors in the margin.[4]

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[4] A. API's assertion that this case involves "minimal" health risks is based on a series of gross distortions of the record, including the following:

i. The epidemiological studies in the record do not, as API maintains, show that there has been "no unexpected incidence of leukemia among workers exposed for many years to low concentrations of benzene" (API Opp. 11), nor do they demonstrate that "no workers are dying of benzene-leukemia." (API Opp. 6). One of the primary reasons, among many, for the Secretary's rejection of API's reliance on those studies was that only a small percentage of the workers included in the studies had actually been exposed to benzene, and the studies made no attempt to ascertain the health status of those particular workers. App. 124a, 182a.

ii. The studies of Drs. Aksoy, Vigliani and Infante did not show that increased incidence of leukemia was eliminated "once benzene exposures were reduced below 100 ppm." (API Opp. 10-11). To the contrary, as the court below noted (App. 8a, n. 13), Drs. Aksoy and Vigliani reported that increased incidence of leukemia vanished once benzene exposures had been *elimina.ed,* not "reduced below 100 ppm." Ex. 60 at 3, Ex. 2-15 at 125. API also misinterpreted the Infante data on this point, as Dr. Infante testified. Tr. 1079-1080.

iii. Particularly misleading is API's effort to characterize the existing PEL of 10 ppm as a level "endorsed" by most scientists, and rejected by the Secretary due to a misreading of the Infante Report. (API Opp. 7-8 and nn. 16, 19). The fact is that in August, 1976—before the Infante Report had been issued—the National Institute for Occupational Safety and Health ("NIOSH") recommended a PEL of 1 ppm and called for the issuance of an emergency temporary standard establishing that limit. Ex. 2-5. The NIOSH recommendation was based, as the court below recognized, on "several additional studies," including those of Aksoy and Vigliani, which had been issued subsequent to NIOSH's original 1971 report on benzene. App. 8a and n. 13. Compare Ex. 2-5 to Ex. 2-3. Moreover, at the benzene hearing virtually every independent public health expert who testified agreed that there is no safe

II

As is plain to all except the signatories of the API memorandum in opposition, the holding of the court below —that in *no* case may the Secretary promulgate a standard until information becomes available by which to quantify

---

level of exposure to benzene, and that exposures should therefore be reduced to the lowest feasible level. See, e.g., Tr. 148-149 (Aksoy), 328 (Sakol), 351-352 (Goldstein), 895 (Infante), 1229 (Liago). As the cited testimony indicates, nothing could be further from the truth than API's attempt to leave the Court with the impression that the authors of the Infante Report regarded a PEL of 1 ppm as unjustified (API Opp. 10). To the contrary, they strongly advocated the 1 ppm PEL.

B. API's efforts to show that the Secretary could have quantified the benefits of the benzene standard as required by the court below are likewise based on a distortion of the record.

i. Contrary to API's assertion (API Opp. 12), OSHA's economic contractor did *not* testify that he could have estimated the benefits of the standard. The contractor testified only that his staff is "qualified to undertake cost effectiveness analysis" (Tr. 512), not that the data exists by which to perform such an analysis with respect to benzene. In point of fact, as the Secretary concluded, the data does not exist. App. 160a. Indeed, the economic contractor upon whom API places such reliance agreed with that conclusion, stating that because of uncertainty as to the dose-response relationship for benzene "it is not possible to quantify incremental health benefits beyond predicting decreased benzene poisoning and a reduced leukemogenic potential from occupational benzene exposures." Ex. 5, p. 3-5. As Dr. Goldwater, a witness for the Manufacturing Chemists Association, stated when he was asked whether it would be practical to estimate the risk created by exposures between 1 ppm and 10 ppm: "Obviously, this is not the sort of thing that one is able to do." (Tr. 2506-2507).

ii. The lack of necessary data is highlighted by the "admittedly preliminary" risk assessment prepared by Dr. Wilson, upon which API places heavy reliance. (API Opp. 13). As the Secretary stated in rejecting the Wilson hypothesis, Dr. Wilson simply "assumed" (App. 161a) the data which, as the court below recognized, is the most critical element of any potential risk assessment: i.e., the dose-response curve. Far from employing "worst-case methodology"

the benefits of the standard and to compare the benefits with the costs (App. 17a-21a)—creates a conflict in the circuits with respect to a crucial issue of law.[5]

Three courts of appeals have held to the contrary, affirming the Secretary's policy of setting the lowest feasible exposure limit for a carcinogen despite an absence of proof as to the extent of the harm caused by low levels of exposure. See HUD Pet. 13-15, discussing *AISI*, *supra*; *Society of Plastics*, *supra*; *Industrial Union Department*, *supra*. In addition, while the court below held that the Secretary must weigh the benefits of a standard against the costs, the prior cases have held that the role "economic considerations are

(API Opp. 13), in making his dose-response assumptions Wilson chose to assume that the Infante data—found by OSHA to be the most reliable—had greatly overstated the risk. Ex. 149B at 19-20, Tr. 2737-2738, 2772-2773. As a result of this and other biases (e.g., Tr. 2742), the Wilson assessment was meaningless. Dr. Wilson's failure to provide the Secretary with the support for his assessment (see Sec. Pet. 15, n. 9) further indicates the utter unreliability of the Wilson projections.

iii. API's assertion that in prior cases there has been greater evidence of the benefits of a low PEL than exists in this case (API Opp. 20-22) is erroneous. In no OSHA case has there been evidence of the effects of a carcinogen at low levels of exposure. What there has been—in this case as well as the others—is evidence of a substantial number of deaths at high exposures. See HUD Pet. 8.

[5] The conflict is recognized not only by the Secretary and HUD, but also by both AISI and Republic Steel Corporation, who were successful petitioners below and unsuccessful petitioners in *AISI* v. *OSHA*, *supra*. See Memorandum Of The American Iron And Steel Institute In Support Of Petitions For A Writ Of Certiorari, and the Response Of Republic Steel Corporation to the petitions, both filed in this case on January 26, 1979.

The circuit conflict was certainly apparent to the parties who recently filed simultaneous petitions for review of the OSHA lead standard in the Third and Fifth Circuits. See HUD Pet. 16. In motion papers filed in those proceedings the Lead Industry Association, which had filed in the Fifth Circuit, has explicitly acknowledged that the courthouse race regarding the lead standard was prompted by the circuit conflict created by the instant decision.

to play in review of the Secretary's standard" is limited to the requirement that a standard must be economically "feasible." *AISI*, *supra*, 577 F.2d at 835-836. See also *Industrial Union Department*, *supra*, 499 F.2d at 478-481;[8] *Society of Plastics*, *supra*, 509 F.2d at 1309.

API attempts to escape the force of this manifest conflict by maintaining that in the prior cases industry's only claim was that a safe level of exposure existed at a point higher than the PEL. That is simply incorrect. For example, in *Society of Plastics*, *supra*, industry argued broadly that the record did not "justify such a low standard", 509 F.2d at 1308, and objected to the costs such a standard would entail, *id.* at 1309. And in *AISI*, industry argued that even if no safe level of exposure exists, the Secretary is obligated to produce evidence that "the specific level" which he adopts as a PEL "is justified on the basis of health need."[7] In a separate brief, Republic Steel Corporation argued that in setting a PEL the Secretary must ascertain "the true risks" of exposures above the PEL, and that "whatever the true risks might be, they must be compared to the benefits. . . ."[8] Republic also challenged the costs of the standard as excessive, and argued that the Secretary should have weighed "the necessity and efficiency of the individual standard."[9] In *Industrial Union*

[8] In *Industrial Union Department* the Secretary had delayed the effective date of the asbestos standard on the basis of a prediction that "no harm is reasonably expected to result from exposures during the transitional period." 499 F.2d at 479, n. 28. The court of appeals, while stating that the Secretary's prediction was not erroneous, noted that the delay nevertheless exposed employees to "some additional risk of disease", and held that the Secretary should have required that all feasible steps be taken to eliminate even that minimal risk. 499 F.2d at 479.

[7] Brief For All Petitioners Other Than Republic Steel Corporation And C F & I Steel Corporation, *AISI* v. *OSHA*, 3d Cir. Nos. 76-2358, et al. (filed May 9, 1977), at 17.

[8] Brief For Petitioner Republic Steel Corporation, *AISI* v. *OSHA*, 3d. Cir. Nos. 76-2358, et al. (filed May 9, 1977), at 38.

[9] *Id.* at 63.

Department, supra, the question of how the benefits of a standard should be weighed in comparison to the costs was also clearly raised and decided. See 499 F.2d at 477-478, 479 and nn. 27, 28.

It is therefore beyond dispute that the construction of the Act articulated in *AISI, Society of Plastics,* and *Industrial Union Department* was carefully considered by the three circuits which decided those cases, and that the decisions cannot be reconciled with the decision of the court below.

CONCLUSION

For the reasons stated in this brief and in the IUD Petition for Certiorari, the petition for certiorari in No. 78-911 should be granted.

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On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF FOR PETITIONER INDUSTRIAL UNION DEPARTMENT, AFL-CIO

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BRIEF FOR PETITIONER INDUSTRIAL UNION DEPARTMENT, AFL-CIO

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-33a)[1] is reported at 581 F.2d 493. The regulation at issue and the

[1] "Pet. App." refers to the appendix to the petition in No. 78-911. The separate Joint Appendix filed in this Court will be cited herein as "A." The transcript of the rulemaking hearings conducted in 1977 prior to the promulgation of the regulation at issue will be cited as "Tr.", and the exhibits received during the rulemaking proceeding will be cited as "Exh." The full record has been lodged with the Clerk, together with an index to the record which has been prepared by the parties for the Court's convenience.

Secretary of Labor's accompanying statement of reasons for the promulgation of the regulation (Pet. App. 34a-252a) appear at 43 Fed. Reg. 5918-5970.

JURISDICTION

The judgment of the court of appeals (Pet. App. 254a-255a) was entered on October 5, 1978 (A. 37). The petition for a writ of certiorari in No. 78-911 was filed on December 7, 1978, and the petition in No. 78-1036 on December 26, 1978. The petitions were granted and the cases consolidated on February 21, 1979 (A. 38-39). The jurisdiction of this Court rests on 28 U.S.C. 1254 (1).

QUESTION PRESENTED

The Occupational Safety and Health Act grants the Secretary of Labor the authority to adopt standards governing the exposure of working men and women to toxic materials and directs the Secretary to

> set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.

The question presented is whether Congress, in enacting this law, intended to preclude the Secretary from promulgating a regulation limiting workers' exposure to a proven carcinogen until such time as substantial evidence becomes available from which to quantify the number of lives that would be saved by the proposed regulation.

STATUTORY PROVISIONS INVOLVED

The Occupational Safety and Health Act of 1970, P.L. 91-596, 84 Stat. 1590, 29 U.S.C. § 651 *et seq.* provides in pertinent part:

§ 2. Congressional statement of findings and declaration of purpose and policy

(a) The Congress finds that personal injuries and illnesses arising out of work situations impose a substantial burden upon, and are a hindrance to, interstate commerce in terms of lost production, wage loss, medical expenses, and disability compensation payments.

(b) The Congress declares it to be its purpose and policy, through the exercise of its powers to regulate commerce among the several States and with foreign nations and to provide for the general welfare, to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources—

* * *

(3) by authorizing the Secretary of Labor to set mandatory occupational safety and health standards applicable to businesses affecting commerce. . . .

§ 3. Definitions

* * *

(8) the term 'occupational safety and health standard' means a standard which requires conditions or the adoption or use of one or more practices, means, methods, operations, or processes reasonably necessary or appropriate to provide safe or healthful employment and places of employment.

§ 6. Standards

* * *

(b)

* * *

(5) The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition

to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired.

* * *

(f) Any person who may be adversely affected by a standard issued under this section may at any time prior to the sixtieth day after such standard is promulgated file a petition challenging the validity of such standard with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such standard. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary. The filing of such petition shall not, unless otherwise ordered by the court, operate as a stay of the standard. The determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole.

STATEMENT OF THE CASE

The Statement in the Brief for the Federal Parties adequately sets forth the facts which are relevant to the disposition of this case. We therefore do not present a separate statement of the case.

SUMMARY OF ARGUMENT

A. In enacting the Occupational Safety and Health Act of 1970 (hereinafter "the Act" or "OSHA"), a particular focus of Congressional attention was the problem of occupational exposure to toxic substances. Congress addressed that problem with the knowledge that the nature and extent of the dangers of such exposure were only partially known, and that more complete knowledge was not imminent given the substantial difficulties in securing necessary information and the delay inherent in the required research.

Congress set the substantive course the Secretary is to follow in promulgating standards dealing with toxic substances in § 6(b)(5) of the Act. That section directs the Secretary, subject only to the constraint of feasibility, to promulgate "*the*" standard that "*most* adequately assures," and that "attain[s] . . . the *highest* degree of health and safety protection for the employee." And, § 6(b)(5) requires the Secretary to "assure," as best can be done, that "*no* employee will suffer material impairment . . . even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life." Further, the Secretary is to act under § 6(b)(5) on the "best *available* evidence" and the "latest *available* scientific data in the field."

The legislative history of § 6(b)(5) shows that Congress meant exactly what the statutory language says. And, the legislative materials relating to OSHA in general establish that while Congress knew full well that the statute would require American industry to make large outlays of money, the legislative judgment was that the cost of adequate health and safety protection at the workplace should be recognized as a cost of doing business and should be reflected in the market place. No legislator espoused the lower court's theory that the protection of worker health should be compromised on the basis of a cost-benefit assessment.

On the facts found by the Secretary, the standard he promulgated is the one required by § 6(b)(5). Benzene is a known leukemogen, which the "best available evidence" shows to be dangerous at any level, and to which thousands of employees are exposed on a regular basis. The only standard which can provide the "assurance" required by the statute to each of the 30,000 employees who are regularly exposed to airborne benzene, and as a result face a prospect of contracting leukemia, is one which requires that exposure to be reduced to the lowest level feasible.

B. The Court below recognized and did not overturn the

Secretary's finding that "benzene was unsafe at any level and . . . that exposures to lower levels of [benzene] would be safer than exposure to higher levels." The court also acknowledged and did not overturn the Secretary's finding that "risk quantification"—i.e., estimation of the number of lives at stake—"at low exposure levels . . . cannot presently be made." The court nevertheless held that the Secretary is without authority to promulgate this standard until he can provide an "educated estimate" or "quantification" of the number of lives that would be saved, and thus establish a basis for comparison of the costs and benefits of the standard.

The court could not and did not reconcile its holding with the directives of § 6(b)(5). The court apparently believed it was relieved of that burden by § 3(8), a subsection of the Act's "Definitions" provision. But § 3(8) embodies no departure from the mandate of § 6(b)(5). As regards standards regulating toxic substances, § 3(8) can have no meaning different from § 6(b)(5); and, however construed, § 3(8) cannot override the explicit directives set forth in § 6(b)(5).

Further, the court below was wrong in treating § 3(8) as "precisely similar" to provisions of the Consumer Product Safety Act ("CPSA"), and in concluding that because a cost-benefit evaluation is required before a CPSA standard can be promulgated, the same must be true of an OSHA toxic substance standard. There is such a requirement under the CPSA because the language and history of that statute call for it; the language and history of OSHA respecting toxic substance standards lead to the opposite conclusion. That difference is no accident, but stems from the Congressional perception that the problems addressed by the two statutes are different in nature. The problem addressed by CPSA was viewed by Congress as involving a mix of countervailing consumer interests. In § 6(b)(5), Congress had the singular purpose of protecting against worker exposure to toxic substances.

ARGUMENT

Introduction

The Secretary of Labor promulgated the standard presently before this Court regulating occupational exposure to benzene after a lengthy informal rulemaking proceeding,[2] which included extensive public hearings and the development of a comprehensive evidentiary record, reflecting not only the views of all interested parties but the existing body of pertinent scientific knowledge and opinion. The core provision of that standard lowers the maximum permissible exposure level of airborne benzene from 10 parts per million (ppm) as an 8-hour time weighted average, which had been the permissible exposure level under a national consensus standard [3] adopted by the Secretary prior to recognition of benzene's carcinogenic effect (Pet. App. 7a-8a), to 1 ppm,

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[2] The standard setting procedure established in Section 6(b)(2)-(4) of the Act is characteristic of the informal rulemaking contemplated by Section 4 of the Administrative Procedure Act, P.L. 89-554, 80 Stat. 383, 5 U.S.C. § 553. By regulation, however, the Secretary has adopted additional provisions requiring that the "hearing examiner [who presides at the oral hearing] shall provide an opportunity for cross-examination [by all interested parties] on crucial issues" and that "[t]he hearing shall be reported verbatim, and a transcript shall be available to any interested person . . ." (29 CFR § 1911-15(b)(2) & (3)). See generally, *Industrial Union Department* v. *Hodgson*, 499 F.2d 467, 472-474 (D.C. Cir. 1974).

[3] Section 3(9) of the Act defines a "national consensus standard" as:

> any occupational safety and health standard or modification thereof which (1) has been adopted and promulgated by a nationally recognized standards-producing organization under procedures whereby it can be determined by the Secretary that persons interested and affected by the scope or provisions of the standard have reached substantial agreement on its adoption, (2) was formulated in a manner which afforded an opportunity for diverse views to be considered and (3) has been

the level determined by the Secretary to be the lowest feasible level. The standard was accompanied by a Statement of Reasons setting out, *inter alia*, nine critical findings that frame the legal issue in this case:

(1) "[T]he accumulated evidence is conclusive that benzene exposure is causally related to the induction of leukemia," a deadly cancer, as well as various other serious and sometimes fatal diseases. Pet. App. at 81a.

(2) Hundreds of employees in this country have died of leukemia from occupational exposure to airborne benzene. Pet. App. at 121a-122a. Although the concentrations of ben-

designated as such a standard by the Secretary, after consultation with other appropriate Federal agencies.

Under § 6(a) of the Act the Secretary was required "as soon as practicable" within the first two years after the Act became effective to promulgate as a legally binding regulation without resort to rulemaking proceedings, "any national consensus standard," unless the Secretary determined that the promulgation of such a standard "would not result in improved safety or health for specifically designated employees."

Congress recognized the defects of the standards that previously had been set by "nationally recognized standards-producing organization[s]" and, accordingly, expected that their use would be short-lived. The House Committee on Education and Labor "determined that . . . the credibility [of these standards] is suspect . . . [because] a private organization is susceptible to the pressures of commercial trade association interests. . . ." (H.R. Rep. No. 91-1291, 91st Cong., 2d Sess. at 18 (1970), reprinted in Committee Print, Legislative History of the Occupational Safety and Health Act of 1970, 92d Cong., 1st Sess. (1971) (hereinafter "Leg. Hist.") at 848). The Senate Committee on Labor and Public Welfare reached a similar conclusion: "Many [national consensus standards] represent merely the lowest common denominator of acceptance by interested private groups" and, as such, "it is essential that [they] be constantly improved and replaced as new knowledge and techniques are developed." (S. Rep. No. 91-1282, 91st Cong., 2d Sess. at 6, Leg. Hist 146).

zene to which those employees were exposed, and the duration of their exposure, cannot be estimated with any certainty, it is likely that the concentrations were for the most part in excess of 10 ppm. Pet. App. at 100a-101a, 104a-105a, 124a.

(3) As respects benzene's leukemogenic effect, there is no level of exposure to benzene which can be considered safe. "From the point of view of choosing a safe level of exposure, therefore, the permissible exposure limit should be set at zero." Pet. App. at 186a. See also Pet. App. at 72a.

(4) Given that until very recently occupational exposure to airborne benzene had been at levels which, while seldom measured, were generally higher than 10 ppm, and that the "latency period" between initial exposure to benzene and manifestation of leukemia is lengthy, often spanning some 20 years (Pet. App. at 116a), there is not now and there could not be for years to come any direct evidence of the number of employees who have died or can be expected to die from leukemia as a result of occupational exposure to benzene at or below the level of 10 ppm. Pet. App. at 182a-183a.

(5) The available data showing the leukemogenic effects of benzene exposure at levels thought to be in excess of 10 ppm do not show the level and length of exposure of the cases studied, and the data understate, to a degree which cannot be determined, the number of leukemia deaths resulting from such exposure.[4] In addition, there is no satisfac-

[4] The Secretary found that in general, there is an under-reporting of benzene-induced leukemia among workers. Pet. App. at 121a.

One reason is that "cases may never be recorded officially because the families refuse[] permission to release the names of the decedents for fear of loss of [workmen's] compensation. . . ." Pet. App. at 103a. (For example, Dr. Marvin Sakol, a noted hematologist, testified that when Ohio law recognized aplastic anemia, but not leukemia, as a disease which could be occupationally induced, death certificates of workers who had died of leukemia sometimes

tory theory of extrapolation from known carcinogenic effects of a substance at high exposure levels to projected carcinogenic effects of the substance at lower exposure levels. Accordingly, there is no adequate scientific basis for estimating the number of leukemia deaths that would result from exposure to benzene at the level 10 ppm or below:

> [T]here does not exist an adequate scientific basis for establishing the quantitative dose response relationship between exposure to benzene and the induction of leukemia and other blood diseases.

Pet. App. at 160a. See also Pet. App. at 182a-183a.

(6) While "it is impossible to derive any conclusions regarding dose-response relationships for benzene . . . [it] is apparent . . . that a decrease in exposure level and/or duration will result in a decreased risk of leukemia." Pet. App. at 183a.

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stated the cause of death as aplastic anemia so that the family would receive compensation. Tr. 311.)

The Secretary further found that in addition many cases go undiagnosed due to the ease with which leukemia can be confused with certain other diseases. Pet. App. at 121a-122a. Similarly, leukemia can produce fatal complications, such as a heart attack, and often the complications rather than the leukemia will be registered as the cause of death. Tr. 307-308.

The Secretary found that underestimating occured even in the most thorough epidemiological study in the record, the study of Dr. Peter F. Infante of NIOSH. Dr. Infante relied exclusively on death certificates to determine the causes of death in the population he studied which, inevitably, for the reasons noted above, caused him to miss cases of leukemia. See Pet. App. at 102a-103a. The Secretary noted that Dr. Sakol had personally observed several cases of leukemia among the workers Dr. Infante studied and whom Dr. Infante incorrectly assumed had died from other causes since their death certificates made no mention of leukemia. *Id.* See also, Exh. 61; Tr. 308-315. Moreover, Dr. Infante was unable to determine whether or not twenty-five percent of the workers included in the group he studied had died. Yet, he assumed for purposes of the study that every one of them was alive. See Pet. App. at 104a.

(7) There are over 30,000 employees in this country who are regularly exposed to airborne benzene at levels in excess of 1 ppm at their workplaces. Pet. App. at 142a-154a.

(8) Current technology provides feasible means to reduce the permissible exposure level of airborne benzene from 10 ppm to 1 ppm in all industries covered by the standard.

(9) Compliance with the standard would entail first-year operating costs in the range of $187 million to $205 million, recurring annual costs of approximately $34 million, and investment in engineering controls of approximately $266 million. These costs would be spread over more than 20 affected industries, with thousands of individual employers, the greatest impact falling on the larger and more stable industries such as the petroleum refinery, petrochemical, and steel industries, and are well within the ability of the regulated industries to bear. Pet. App. at 134a. See also *id.* at 142a-154a.

The court below, recognizing that under § 6(f) of the Act the factual findings of the Secretary "shall be conclusive if supported by substantial evidence in the record considered as a whole,"[5] did not upset any of these findings. Rather, the court held that these findings are not sufficient to justify the Secretary's decision to reduce the permissible exposure level from 10 ppm to 1 ppm. The court ruled that the Secretary cannot promulgate an occupational health standard without finding a "reasonable[] . . . relationship between expected costs and benefits"; that since the Secretary did not make an "educated estimate[] of the extent of benefits" to be gained by reducing the permissible exposure level, it is "impossible to assess the reasonableness of [that] relationship. . . ."; and, therefore, that unless and until the Secretary can make such an educated estimate of the number of leukemia deaths that would be avoided by the reduction in the permissible exposure level for benzene, he is

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[5] See Pet. App. at 4a-5a.

without statutory authority to promulgate a standard reducing the present permissible exposure level. Pet. App. at 21a.

The court based its analysis on the language in § 3(8), the subsection of the Act's "Definitions" section which states the general definition of an "occupational safety and health standard." Specifically, the court found the requirement of a cost-benefit assessment, entailing an "educated" projection of the number of lives that would be saved, in the inclusion of the words "reasonably necessary or appropriate" in § 3(8). For its interpretation of those words, the court relied upon *Aqua Slide 'N' Dive Corp.* v. *Consumer Product Safety Commission,* 569 F.2d 831 (5th Cir. 1978), a decision interpreting a provision of the Consumer Product Safety Act ("CPSA")[6] containing the words "reasonably necessary."

The pertinent statutory materials, however, are § 6(b)(5), the provision which establishes the substantive criteria for the issuance of toxic substance standards, and its legislative history. Those materials leave no doubt that given the Secretary's findings the Act mandated the standard he issued.

A. Section 6(b)(5) Of OSHA, The Provision Which Governs The Setting Of Toxic Substance Standards, Authorizes The Benzene Standard Promulgated By The Secretary.

1. OSHA represents a Congressional judgment that the human and economic costs[7] of occupational injuries and

[6] P.L. 92-573, 86 Stat. 1207, 15 U.S.C. § 2051 *et seq.*

[7] Section 2(a) of the Act contains this statement of "Findings and Purpose":

> The Congress finds that personal injuries and illnesses arising out of work situations impose a substantial burden upon, and are a hindrance to, interstate commerce in terms of lost production, wage loss, medical expenses, and disability compensation payments.

diseases are of such dimension and that the responses of the states to this urgent problem have been so inadequate that comprehensive federal regulation is required. See generally, *Atlas Roofing Co.* v. *Occupational Safety Comm'n,* 430 U.S. 442, 444-445 (1977). Section 2(b) of the Act states the Congressional purpose in unequivocal terms: "The Congress declares it to be its purpose and policy . . . to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources. . . ."

A particular focus of Congressional attention was the problem of occupational exposure to toxic substances. Thus, the report of the Senate Committee on Labor and Public Welfare, in recommending Senate passage of the bill, gave particular emphasis to the need to protect employees from workplace exposure to such substances:

> In the field of occupational health the view is particularly bleak, and, due to the lack of information and records, may well be considerably worse than we currently know.
>
> Occupational diseases which first commanded attention at the beginning of the Industrial Revolution are still undermining the health of workers. Substantial numbers, even today, fall victim to ancient industrial poisons such as lead and mercury. Workers in the dusty trades still contract various respiratory diseases. Other materials long in industrial use are only now being discovered to have toxic effects. In addition, technological advances and new processes in American industry have brought numerous new hazards to the workplace. Carcinogenic chemicals, lasers, ultasonic energy, beryllium metal, epoxy resins, pesticides, . . . all present incipient threats to the health of workers. Indeed, new materials and processes are being introduced into industry at a much faster rate than the present meager resources of occupational health can keep up with. It is estimated that every 20 minutes a new and potentially toxic chemical is introduced into industry. New processes and new sources of energy present occupational health problems of unprecedented complexity.

> Recent scientific knowledge points to hitherto unsuspected cause-and-effect relationships between occupational exposures and many of the so-called chronic diseases—cancer, respiratory ailments, allergies, heart disease, and others. In some instances, the relationship appears to be direct: asbestos, ionizing radiation, chromates, and certain dye intermediaries, among others, are directly involved in the genesis of cancer. In other cases, occupational exposures are implicated as contributory factors. The distinction between occupational and non-occupational illnesses is growing increasingly difficult to define.
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> In 1966-67, the Surgeon General of the United States studied six metropolitan areas, examining 1,700 industrial plants which employed 142,000 workers. The study found that 65 percent of the people were potentially exposed to harmful physical agents, such as severe noise or vibration, or to toxic materials. The Surgeon General further examined controls that were in effect to protect workers from such hazards, and found that only 25 percent of the workers were adequately covered.

S. Rep. No. 91-1282, *supra* at 2-3, Leg. Hist. 142-143. The same concerns were also the focus of attention in the House of Representatives. See H.R. Rep. No. 91-1291, *supra* at 14-16, Leg. Hist. 844-846.[8]

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[8] See also S. Rep. No. 91-1282, *supra* at 19-20 (Leg. Hist. 159-160); Leg. Hist. 1044-1045, 1087, 517, 518-519, 337-339, 445-446, 1084. The Senate Report noted "the lack of information and records" regarding occupational disease (S. Rep. No. 91-1282, *supra* at 2, Leg. Hist. 142), and several legislators echoed the concern voiced by Representative Daniels that "[r]ecords do not exist, on any meaningful basis, regarding the creeping death and disability caused by plant environmental hazards to the health * * * [p]articularly the insidious 'silent killers' such as toxic fumes. . . ." Leg. Hist. 1003. See also Leg. Hist. 1044-1045, 319, 1084, 445, 518, 1087. Congress recognized that information regarding the effects of exposure to toxic substances is particularly difficult to obtain where lengthy latency periods are involved. See Leg. Hist. 1087, 415. And cf. S. Rep. No. 91-1282, *supra* at 4 (Leg. Hist. 144) (possibility of workmen's compensation liability does not induce employers to reduce exposures to toxic substances which have long latency periods, because the eventual disease will seldom be traceable to exposures which occurred many years in the past).

Congress thus understood that the nature and extent of the dangers of occupational exposure to toxic substances were only partially known, and that more complete knowledge was not imminent given the substantial difficulties in securing necessary information and the delay inherent in the required research. Thus informed, Congress chose a standard setting scheme to maximize its overriding goal—employee protection. Section 6(b)(5) sets the substantive course the Secretary is to follow "in promulgating standards dealing with toxic materials or harmful physical agents":

> The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired.

It is difficult to conceive of language conveying a more complete dedication to a single purpose. Subject only to the constraint of feasibility—*viz.* what is "capable of being

done, executed or effected; possible of realization''[9]—the Secretary is to promulgate *''the''* standard that *''most* adequately assures,'' and that ''attain[s,] . . . the *highest* degree of health and safety protection for the employee.'' And, § 6(b)(5) requires the Secretary to ''assure,'' as best can be done, that *''no* employee will suffer material impairment . . . even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.''

Congress did not simply pass a statute that promised protection in theory; recognizing the limits of scientific knowledge, § 6(b)(5) directs the Secretary to act on the ''best *available* evidence'' and the ''latest *available* scien-

[9] Webster's Third New International Dictionary 831 (1961). Lower courts have held that in some circumstances a standard may be so ''prohibitively expensive'' as to be infeasible. See *Industrial Union Department* v. *Hodgson*, 499 F.2d 467, 477-481 (1974); *American Iron & Steel Institute* v. *OSHA*, 577 F.2d 825, 832-837 (3rd Cir. 1978), *petitions for cert. pending*, Nos. 78-918, 78-919. The correctness of those rulings, and the precise contours of the feasibility requirement, are not at issue in this case; for in the court of appeals, respondents did not contend that the benzene standard would result in any adverse consequences whatsoever to their businesses. They merely asserted that the costs involved were significant, and that the standard had not been shown to be worth the costs. Both the plain meaning of § 6(b)(5) and its legislative history, which we discuss at pp. 17-23, *infra*, establish that respondents' contentions, even if true, would not render the standard infeasible within the meaning of § 6(b)(5). In this connection, see generally *Industrial Union Department, supra; American Iron & Steel Institute, supra.; Society of The Plastics Industry, Inc.* v. *OSHA*, 509 F.2d 1301, 1308-1309 (2d Cir.), *cert denied*, 421 U.S. 992 (1975). Cf. *Southern Colorado Prestress Co.* v. *OSHRC*, 586 F.2d 1342, 1351 (10th Cir. 1978); *Arkansas-Best Freight Systems, Inc.* v. *OSHRC*, 529 F.2d 649, 653-654 (8th Cir. 1976). But cf. *RMI Co.* v. *Secretary of Labor*, — F.2d —, 7 BNA OSHC 1119 (6th Cir., March 13, 1979); *Turner Co.* v. *Secretary of Labor*, 561 F.2d 82 (7th Cir. 1977).

tific data in the field.'' As the Report of the House Committee on Education and Labor states: ''The Committee feels it is vital that when the Secretary sets an occupational health standard he do so on the basis of the best available professional evidence; it is not intended that the Secretary be paralyzed by debate surrounding diverse medical opinions.'' H.R. Rep. No. 91-1291, *supra* at 18, Leg. Hist. 848. In the words of the late Mr. Justice Clark, sitting by designation on the Court of Appeals for the Second Circuit, ''[u]nder the command of OSHA, it remains the duty of the Secretary to act to protect the workingman, and to act even in circumstances where existing methodology or research is deficient.'' *Society of The Plastics Industry, Inc.* v. *OSHA*, 509 F.2d 1301, 1308 (2d Cir.), *cert. denied*, 421 U.S. 992 (1975). See also *Industrial Union Department* v. *Hodgson*, 499 F.2d 467, 475 (D.C. Cir. 1974); *American Iron & Steel Institute* v. *OSHA*, 577 F.2d 825 (3rd Cir. 1978), *petitions for cert. pending*, Nos. 78-918, 78-919.

2a. The evolution of § 6(b)(5) shows that Congress meant exactly what the statutory language says.

House and Senate consideration of OSHA proceeded on virtually a simultaneous schedule. In the House the Act began as ''the Daniels bill,'' H.R. 16785; in the Senate it was introduced as ''the Williams bill,'' S. 2193. Neither bill contained a provision setting the criteria governing the issuance of toxic substance standards.[10] That provision was added to each measure in committee.[10a]

The provision governing issuance of toxic substance standards reported by the House Committee on Education

[10] See Leg. Hist. 721, 728-732 (Daniels bill), 1, 6-7 (Williams bill).

[10a] The provisions added by the two committees were applicable to all standards (see materials cited in notes 11 and 12, *infra*), but the provisions were ultimately amended to apply solely to standards for toxic substances and harmful physical agents. See note 21, *infra*.

and Labor on July 9, 1970, contained no limitation of "feasibility." The Secretary was to be required to

> set the standard which most adequately assures, on the basis of the best available professional evidence, that no employee will suffer any impairment of health or functional capacity, or diminished life expectancy even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.[11]

On October 6, 1970, the Senate Committee on Labor and Public Welfare reported out virtually the same provision but with one significant change: the words "and feasibly" were added so that the Secretary's mandate was to "set the standard which most adequately *and feasibly* assures. . . ." [12] This additional language resulted from an amendment offered in Committee by Senator Javits, the ranking Republican and a key figure throughout the Senate's deliberation on OSHA.[13] Senator Javits explained that his amendment "was an improvement over the Daniels bill [because the latter as reported out of committee in the House] might be interpreted to require *absolute* health and safety in all cases, regardless of feasibility. . . ." [14]

The Senate Committee report that accompanied S. 2193 made clear its understanding of the added language of feasibility by paraphrasing the bill's language in the following terms:

[11] H.R. Rep. No. 91-1291, *supra* at 4, Leg. Hist. 834.

[12] Leg. Hist. 204, 242.

[13] See e.g., Leg. Hist. 1151.

[14] S. Rep. No. 91-1282, *supra* at 58 (individual views of Senator Javits), Leg. Hist. 197 (emphasis added). Senator Javits described his "feasibility" amendment as an improvement over not only the Daniels bill, but also "the Administration bill which contain[ed] no criteria for standards at all." *Ibid.* That bill, S. 2788, had been introduced by Senator Javits on August 6, 1969. See S. Rep. No. 91-1282 at 5, Leg. Hist. 145. Its provisions regarding the setting of standards appear at Leg. Hist. 31, 36-42.

> [S]tandards should be directed at assuring, *so far as possible*, that no employee will suffer impaired health or functional capacity, or diminished life expectancy, by reason of exposure to the hazard involved, even though such exposure may be over the period of his entire working life." [15]

The "feasibility" language reported by the Committee was refined on the floor of the Senate. Notwithstanding the Javits amendment, several Senators—most notably Senator Dominick, the Nixon Administration spokesman on OSHA, and a prominent force in the ultimate development of the legislation [16]—expressed concern that § 6(b)(5) could nevertheless be read to accomplish what Senator Javits had sought to avoid. Senator Dominick explained (Leg. Hist. 367):

> [Section 6(b)(5)] is inherently confusing and unrealistic. It could be read to require the Secretary to ban all occupations in which there remains *some* risk of injury, impaired health, or life expectancy. In the case of all occupatons, it will be impossible to eliminate all risks to safety and health. Thus, the present criteria could, if literally applied, close every business in this nation. In addition, in many cases, the standard which might most 'adequately' and 'feasibly' assure the elim-

[15] S. Rep. No. 91-1282, *supra* at 7, Leg. Hist. 147 (emphasis added).

[16] Senator Dominick was the sponsor of S. 4404, introduced on behalf of the Nixon Administration as a substitute for S. 2193 after it became apparent that the latter bill would be reported out of the Committee on Labor and Public Welfare. See Leg. Hist. 73, 510. On the Senate floor, the Dominick substitute was tabled by the narrow vote of 41 to 39 the day before S. 2193 was passed. Leg. Hist. 448-450. Senator Dominick's prominent role in the development of the legislation was noted by his fellow Senators. For example, Senator Javits observed that Senator Dominick's "efforts had a vital impact on the bill in terms of principle and fairness. . . ." Leg. Hist. 526. See also Leg. Hist. 527 (remarks of Senator Williams).

> ination of the danger would be the prohibition of the occupation itself. [Emphasis in original.]

In light of that concern, Senator Dominick proposed an amendment to delete from § 6(b)(5) the entire sentence setting forth the criteria for the promulgation of standards.[17]

Throughout the floor debate that ensued, Senator Dominick time and again cautioned his colleagues about what he perceived to be the problem with enacting § 6(b)(5) as drafted in the Committee bill. His remarks were consistently directed at the same concern: that the language proposed by the Committee could be read as requiring an absolutely risk-free workplace—a requirement which could be met only by shutting down numerous plants and facilities or, indeed, entire industries, and by banning numerous occupations.[18] He gave the following example (Leg. Hist. 423):

[17] Amendment No. 1054, Leg. Hist. 365-666.

[18] It is unrealistic to attempt, as [§ 6(b)(5)] apparently does, to establish a utopia free from any hazards. Absolute safety is an impossibility and it will only create confusion in the administration of this act for the Congress to set clearly unattainable goals.

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> The difficulty of the language I am dealing with here and that I am trying to delete is the requirement that the Secretary, in establishing standards, must assure that there will not be any risk at all.
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> * * *
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> Almost any kind of occupation one can think of has something which is inherently hazardous simply by the fact that one is living and breathing and there is no way a criteria [sic] can be established so that an employee would not be faced with some risk for the period of his working life.
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> * * *
>
> Let us take the case of a bus driver. There is no possible way that a bus driver for the rest of his life could be assured that

> How in the world, . . . during a working day of any one driving a bus . . . can we set standards that will make sure he will not have any risk to his life for the rest of his life? It is totally impossible for this to be put in a bill; and yet it is in the committee bill.

No concern of any other nature with regard to § 6(b)(5) was raised by any Senator. And while Senator Dominick declared that standards could not be expected "to produce a perfect environment" because "[n]o human effort can [do so] no matter how hard we try," he endorsed the principle that standards should nonetheless "be as effective as possible."[19] This view that the Secretary was to require what is "possible," not what is perfect, in fact reflected the consensus in the Senate. When that became apparent, the chief spokesmen on both sides of the aisle—Senators Williams, Javits and Dominick—translated that consensus into a modification of the Committee's version of § 6(b)(5) which was "agreeable to all."[20]

That modification was embodied in a substitute amendment, introduced by Senator Dominick, consisting of the language of § 6(b)(5) as eventually enacted. In the colloquy immediately preceding passage of that amendment, Senators Dominick and Williams confirmed the amendment's purpose (Leg. Hist. 502-503):

> he is not going to get regular exposure to these hazards. By the very nature of driving a bus over the road, no matter how many safety tires and signals are on the bus, it is a hazardous occupation.

Leg. Hist. 480-481. See also Leg. Hist. 345-346, 400-401.

[19] Leg. Hist. 376. See also Leg. Hist. 348 (remarks of Senator Saxbe, following colloquy with Senator Dominick in support of the latter's criticism of § 6(b)(5)): "[W]e still have to make every effort to make the place of employment not only as safe as possible, but also a place where the effectiveness is not impaired, the work is not impaired, by fear of dangerous fumes or accidents. . . ."

[20] Leg. Hist. 502.

MR. DOMINICK: . . .

What we were trying to do in the bill—unfortunately, we did not have the proper wording or the proper drafting—was to say that when we are dealing with toxic agents or physical agents, we ought to take such steps as are feasible and practical to provide an atmosphere within which a person's health or safety would not be affected. Unfortunately, we had language providing that anyone would be assured that no one would have a hazard, . . . no one would have any problem for the rest of his working life.

It was an unrealistic standard. As modified, we would be approaching the problem by looking at the problem and setting a standard or criterion which would not result in harm.

* * *

It is my understanding, if I may say so, that what we are doing now is to say that the Secretary has got to use his best efforts to promulgate the best available standards, and in so doing, that he should take into account that anyone working in toxic agents or physical agents which might be harmful may be subjected to such conditions for the rest of his working life, so that we can get at something which might not be toxic now, if he works in it a short time, but if he works in it the rest of his life it might be very dangerous; and we want to make sure that such things are taken into consideration in establishing standards; is that correct?

* * *

MR. WILLIAMS of New Jersey: That is exactly correct. . . . I think it is clear, the objectives have been stated, and it strengthens the objectives of standards that will protect against physical impairment and loss of function. [21]

[21] To the same end, the Committee version of § 6(b)(5) was revised to reflect the Congressional understanding that work of any nature necessarily has an impact on the human body and, ultimately, on life expectancy, and to seek to eliminate all such effects would amount to a ban on all employment. In this connection, Senator Dominick stated that "[s]imply being in a work environment where one is responsible for certain duties . . . produce[s] in most people impaired health, and it certainly diminishes life expectancy to some extent." Leg. Hist. 376. In the same vein, Senator Saxbe noted that "[w]orking itself is apt to diminish one's life expectancy. If one wants to stay home in bed, he probably will live longer than by standing at the plant and doing his job." Leg. Hist. 337.

Section 6(b)(5) was therefore modified to refer to "material impairment" rather than "any impairment," to delete the vague concept of "diminished life expectancy," and to apply only to toxic substances and harmful physical agents, rather than to every type of hazard that might be encountered on the job.

[22] Leg. Hist. 1092-1118.

As so amended, the Senate passed S. 2193 on November 17, 1970. The House, meanwhile, passed a substitute bill which contained no criteria to govern the setting of toxic substance standards.[22]

In conference, the House receded and accepted § 6(b)(5) precisely as the Senate had passed it. In receding, the House insisted on an amendment which became § 6(b)(6)(A). As described in the Conference Report, that section provides:

> that employers may petition for a temporary variance from an occupational health or safety standard if they are unable to comply with a standard for the following limited reasons: unavailability of professional or technical personnel or of necessary materials or equpment or because necessary construction or alteration of facilities cannot be completed in time. Economic hardship is not to be a consideration for the qualification for a temporary extension order.

H.R. Rep. No. 91-1765, 91st Cong., 2d Sess. 35 (1970), Leg. Hist. 1188. That the House insisted on this provision in accepting § 6(b)(5) is consistent with the fact that Congress understood § 6(b)(5) to call for the highest degree of protection of worker health, subject only to the impossibility of compliance by regulated employers.

b. A more general review of the legislative materials

relating to OSHA's enactment discloses that while Congress knew full well that the statute would require American industry to make large outlays of money, the legislative judgment was that the cost of adequate health and safety protection at the workplace should be recognized as a cost of doing business and should be reflected in the market place.

Senator Williams, who introduced the initial Senate version of the bill and served as floor manager, explained the economic philosophy of OSHA as follows: "We know the costs w[ill] be put into consumer goods but that is the price we should pay for the 80 million workers in America." [23]

Senator Eagleton, another proponent, added:

> The costs that will be incurred by employers in meeting the standards of health and safety to be established under this bill are, in my view, reasonable and necessary costs of doing business. Whether we, as individuals, are motivated by simple humanity or by simple economics, we can no longer permit profits to be dependent upon an unsafe or unhealthy worksite.[24]

The judgment that the costs of employee health and safety should be spread through the economy, rather than be borne by individuals, was well-expressed by Senator Yarborough, a co-sponsor of the bill in the Senate, in response to interest group complaints that such legislation would prove too expensive:

> One may well ask too expensive for whom? Is it too expensive for the company who for lack of proper safety equipment loses the service of its skilled employees? Is it too expensive for the employee who loses his hand or leg or eyesight? Is it too expensive for the widow trying to raise her children on meager allowance under workmen's compensation and social security? And what about the man—a good hardworking man—tied to a wheel chair or hospital bed for the rest of his life? That is what we are dealing with when we talk about industrial safety.
>
> We should have uniform standards so that no one industry would gain an advantage over any other industry. It would be far cheaper for our economy. It would save money in workmen's compensation premiums.
>
> We are talking about people's lives, not the indifference of some cost accountants. We are talking about assuring the men and women who work in our plants and factories that they will go home after a day's work with their bodies intact. We are talking about assuring our American workers who work with deadly chemicals that when they have accumulated a few years seniority they will not have accumulated lung congestion and poison in their bodies, or something that will strike them down before they reach retirement age.[25]

The legislative materials reveal no dissent from the approach stated by these Senators. No legislator espoused the lower court's theory that the protection of worker health should be compromised on the basis of a cost-benefit assessment.

Congress was fully aware of the consequences of its determination. Congress realized, for example, that the additional costs of doing business that would be required to comply with OSHA standards might threaten the viabil-

[23] Leg. Hist. 444.

[24] Leg. Hist. 1150-1151.

[25] Leg. Hist. 510. See also, e.g., Leg. Hist. 1030-1031 (remarks of Representative Dent):

> Although I am very much disturbed over adding new costs to the operation of our production facilities . . . I would say there is a greater concern and that must be for the production men who do the producing—the men who work in the service industries and the men and women who daily go out and keep the economy moving and make it safe for all of us to live and to work and to be able to prosper in it.

ity of a great number of small employers. The legislative response was not, however, to dilute the mandate of § 6(b)(5) (or the other substantive provisions of the Act) or to exempt small employers from its reach. Rather, Congress established in § 28 of the Act [26] a program to provide loans to small businesses to be used to achieve compliance with the standards promulgated by the Secretary. Senator Dominick stated the intent of § 28 in these words:

> [The small business program] permits the Secretary to make loans to small businesses wherever the standards that are set by the National Government are so severe as to have caused a real and substantial economic injury. Under those circumstances the Secretary is entitled, through the Small Business Administration, to make loans to those businesses to get them over the hump, because of the need for the new equipment, or because of new conditions within the shop, which would permit them to continue in operation.
>
> I think this is a very significant and important provision for minimizing economic injury which could occur if the bill resulted in situations which would have very serious effects on businesses.

Leg.Hist. 525.

Congress thus expected whatever costs were necessary to provide the protections called for by the Act to be borne through the market mechanism as part of the true costs to society of the production of certain goods.

3. On the facts found by the Secretary, the standard he promulgated is the one required by § 6(b)(5). Given that benzene is a known leukemogen, which the "best available evidence" shows to be dangerous at any level of exposure, and to which thousands of employees are exposed on a regular basis, the Secretary's duty under § 6(b)(5) is unambiguous: subject only to the constraint of feasibility, he "shall set *the* standard which *most adequately assures* . . . ,

[26] As amended, 42 U.S.C. § 3142-1, 15 U.S.C. § 636(b)(5).

on the basis of the best available evidence, that *no employee* will suffer material impairment of health or functional capacity *even if* such employee has regular exposure to the . . . [regulated substance] for the period of his working life." Here, the only standard which can provide the "assurance" required by the statute to each of the 30,000 employees who are regularly exposed to airborne benzene, and as a result face a prospect of contracting leukemia, is one which requires that exposure to be reduced to the lowest level feasible.

B. Section 3(8), The Definitional Provision Relied Upon By The Court Below, Does Not Provide For Any Departure From The Specific Directives Of § 6(b)(5).

The court below nonetheless held that the Secretary was without authority to promulgate this standard, because he did not provide an "educated estimate" or "quantification" of the number of lives that would be saved and thus did not establish a basis for comparison of the costs and benefits of the standard. The court recognized that the Secretary had found, based on the conclusion of NIOSH and the general agreement of the experts who testified, that, in the court's words, "benzene was unsafe at any level and . . . that exposures to lower levels of [benzene] would be safer than exposure to higher levels." Pet. App. at 17a-18a. The court also acknowledged, and did not overturn, the Secretary's finding that, again in the court's words, "risk quantification"—i.e., estimation of the number of lives at stake—"at low exposure levels and therefore estimates of expected benefits from the standard cannot presently be made. . . ." Pet. App. at 19a, n. 23.[27] Nevertheless, the court ruled that

[27] While accepting OSHA's finding, the Court stated that (Pet. App. at 19a, n. 23):

> Although OSHA's assertion that present knowledge is insufficient to construct a valid dose-response curve for benzene may be correct, the record reflects that preliminary assessments

the Secretary could not require that the permissible exposure limit be reduced to an admittedly safer level "[u]ntil such estimates are possible." Pet. App. at 21a.[28]

The court below could not and did not reconcile its holding with the directives in § 6(b)(5). See Pet. App. at 15a-16a, 21a. The court apparently believed it was relieved of that burden by § 3(8) of the Act. Section 3(8), a subsection of

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are now being made and that valid extrapolations will be possible as more is known about the effects of past exposure at higher levels.

Contrary to the court's observation of what the record "reflects," no witness for any party suggested that reliable data as to past exposures of groups of employees were likely to be discovered; nor did any party make that representation to the court below. As the Secretary found, "it is extremely difficult to reconstruct and define employee exposures retrospectively." Pet. App. at 182a. That finding is borne out by the fact that even the most extensive and carefully conducted studies of the effects of past benzene exposure lack data as to the levels and duration of exposures involved. See Pet. App. at 104a-105a. Moreover, even if such data were available, the estimates required by the court of appeals still could not be made, due to the absence of other necessary data such as the actual number of leukemia cases which have resulted from past exposures. See pp. 9-10 and note 4, *supra*. The court of appeals recognized that in the absence of any data concerning past human exposure sufficient to provide the information required by its opinion, the only way to seek that information without "wait[ing] until deaths occur as a result of exposure at levels below 10 ppm" is to await reliable studies of animal exposure. See Pet. App. at 20a-21a. But as the court acknowledged, scientists have encountered difficulties in inducing benzene leukemia in animals (Pet. App. at 20a, n. 25); and consequently there is no prospect that this route will yield the information which the court held the Secretary must obtain.

[28] The court stated that this ruling "does not mean that OSHA must wait until deaths occur as a result of exposure at levels below 10 ppm before it may validly promulgate a standard reducing the permissible exposure level." Pet. App. at 20a. But the record does not establish any other basis on which the court's required estimates could realistically be made. See note 27, *supra*.

the Act's "Definitions" provision, reads as follows:

> The term "occupational safety and health standard" means a standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment.

The court construed the words "reasonably necessary" in § 3(8) to require the Secretary to perform a cost-benefit assessment as a prerequisite to the promulgation of a toxic substance standard. By the logic of the court's opinion, that requirement would obtain regardless of anything in § 6(b)(5) to the contrary. But as we now show, § 3(8) embodies no such departure from the mandate of § 6(b)(5).

The words "reasonably necessary" cannot be understood without reference to the words which follow them in § 3(8): "to provide safe or healthful employment and places of employment." The latter words in turn derive their meaning from the more specific objectives and criteria set forth in the Act. In the case of a toxic substance, that meaning is stated in § 6(b)(5): employment and places of employment are "healthful" where there is the most adequate assurance feasible that no employee will suffer a material impairment of health from exposure to the toxic substance, even if the exposure is regular and prolonged. Thus, as regards standards regulating toxic substances, § 3(8) can have no meaning different from § 6(b)(5).[29]

However construed, § 3(8) cannot override the explicit

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[29] As this Court has frequently held, provisions which assert that regulations are to be "necessary" or "appropriate" to achieving a statutory objective are not to be construed as imposing a discrete substantive requirement. *Mourning* v. *Family Publications Service, Inc.*, 411 U.S. 356, 369 (1973); *Thorpe* v. *Housing Authority*, 393 U.S. 268, 277, 280-281 (1969); *United States* v. *Allegheny-Ludlum Steel Corp.*, 406 U.S. 742, 748-749 (1972); *United States* v. *Bacto-Unidisk*, 394 U.S. 784, 786-787 and n. 2, 791-792 (1969).

directives which Congress set forth in § 6(b)(5).

> "General language of a statutory provision, although broad enough to include it, will not be held to apply to a matter specifically dealt with in another part of the same enactment."

Ginsberg & Sons v. *Popkin*, 285 U.S. 204, 208 (1932).[30] Particularly is that so here, where the legislative history shows that Congress understood § 6(b)(5) to be the exclusive enumeration of the factors governing the setting of toxic substance standards. See *supra* at 17-23. Thus, for example, S. 2193, the bill to which § 6(b)(5) was added in the Senate, contained the provision which became § 3(8).[31] Yet, the Senate debated at length the question whether § 6(b)(5), before its final amendment, might be read to require "absolute health and safety in all cases." See *supra* at 18-22.[32] Had Congress understood § 3(8) as the Fifth Circuit does, that entire debate would have been beside the point. The lesson to be drawn is that Congress did not intend § 3(8) to have the significance ascribed to it by the court below.

Even if the "reasonably necessary" language of § 3(8) were assumed to have some independent meaning which could override the terms of § 6(b)(5), there is no basis for attributing to it the particular meaning announced by the court below: that a standard can be "reasonably necessary" only if it can survive a "cost-benefit" evaluation. The asserted basis for this interpretation was the Fifth Circuit's *Aqua Slide* decision construing requirements of the Consumer Product Safety Act, which the court below deemed

[30] See also *FPC* v. *Texaco*, 417 U.S. 380, 394-395 (1974); *Clark* v. *Uebersee Finanz-Korp.*, 332 U.S. 480, 488-489 (1947).

[31] Leg. Hist. 204, 235.

[32] Senator Javits described another bill (S. 2788, which he had introduced) as containing "no criteria for standards at all" (Leg. Hist. 197), even though that bill contained a provision virtually identical to § 3(8) (Leg. Hist. 31, 35).

to be "precisely similar" to the requirements of OSHA. Pet. App. at 15a. But far from being "precisely similar," the language and purpose of the CPSA provisions discussed in *Aqua Slide* are fundamentally different from that of § 3(8), OSHA, and this difference highlights the error of the result reached by the court below.[33]

The provisions at issue in *Aqua Slide* were expressly intended to govern the CPSA standard setting process. Section 7(a) of the CPSA limits the authority of the Consumer Product Safety Commission ("CPSC") to promulgate standards as follows:

> Any requirement of such a standard shall be reasonably necessary to prevent or reduce an unreasonable risk of injury associated with such product.

And § 9(c)(2)(A) sets forth a finding which the CPSC must make before promulgating a standard:

> (2) The Commission shall not promulgate a consumer product safety rule unless it finds (and includes such finding in the rule)—
>
> (A) that the rule (including its effective date) is reasonably necessary to eliminate or reduce an unreasonable risk of injury associated with such product;....

As the court in *Aqua Slide* recognized, the source of the required cost-benefit assessment under CPSA is the term "unreasonable risk," not the term "reasonably necessary." 569 F.2d at 839. The concept of "unreasonable risk" as used in the CPSA inherently involves some balancing between "costs" and "benefits": it requires on the one hand, an assessment of the nature and extent of the hazard posed by a particular consumer good; and, on the other, an evaluation of the effect of removal of the hazard upon the utility

[33] See McGarity, Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA, 67 Geo. L. J. 729, 786-787 (1979).

and cost of the good. In that balance lies the judgment whether the risk is "reasonable." See *Forester* v. *Consumer Product Safety Commission*, 559 F.2d 774, 789 (D.C. Cir. 1977).

The legislative history of CPSA directly confirms this interpretation. See H.R. Rep. No. 92-1153, 92d Cong., 2d Sess. 33 (1972); S. Rep. No. 92-749, 92d Cong., 2d Sess. 6, 14-15 (1972). What is more, the statute itself expressly sets forth the factors that are to be considered in weighing the costs and benefits of a CPSA standard. The statute provides that the CPSC, "prior to promulgating" a standard, "shall consider" and "shall make appropriate findings" as to, *inter alia*: "the degree and nature of the risk of injury the rule is designed to eliminate or reduce"; and "the need of the public for the consumer products subject to such rule, and the probable effect of such rule upon the utility, cost, or availability of such products to meet such need." § 9(c)(1)(A), (C).

The court below was therefore wrong in concluding that because a cost-benefit evaluation is required before a CPSA standard can be promulgated, the same must be true of an OSHA toxic substance standard. There is such a requirement under CPSA because the language and history of the statute call for it; the language and history of OSHA respecting toxic substance standards lead to the opposite conclusion. That difference in result is no mere accident of statutory draftsmanship. It stems from the Congressional perception that the problems addressed by the two statutes are different in nature.

The problem addressed by CPSA was viewed by Congress as involving a mix of countervailing consumer interests. See, *e.g.*, CPSA § 9(c)(1)(C). The fact that a consumer product may be dangerous is not alone sufficient to justify its regulation, since such regulations might well adversely affect "the product's utility, cost and availability to the

consumer."[34] For example, Congress recognized that while sharp knives are dangerous, consumers would not gain from a regulation requiring that knife blades be dulled.[35] Congress directed the CPSC to engage in the process of balancing these competing consumer interests before regulating any consumer product.

Congress saw the problem of worker exposure to toxic substances in a different light. Congress viewed such exposure as intolerable where it could possibly be avoided. Section 6(b)(5) had the singular purpose of protecting against such exposure. Congress chose not to balance that purpose against the costs of achieving that protection. The language of § 6(b)(5) translates that judgment into a mandate to the Secretary to achieve the highest degree possible of employee protection from toxic substances.

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[34] H.R. Rep. No. 92-1153, *supra* at 33.

[35] S. Rep. No. 92-749, *supra* at 6-7.

CONCLUSION

For the reasons stated herein, the decision of the Fifth Circuit should be reversed insofar as it invalidates the reduction in the permissible exposure limit and the provisions related thereto.

Respectfully submitted,

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In the Supreme Court of the United States

OCTOBER TERM, 1978

INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
PETITIONER

v.

AMERICAN PETROLEUM INSTITUTE, ET AL.

RAY MARSHALL, SECRETARY OF LABOR, PETITIONER

v.

AMERICAN PETROLEUM INSTITUTE, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

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In the Supreme Court of the United States

OCTOBER TERM, 1978

No. 78-911

INDUSTRIAL UNION DEPARTMENT, AFL-CIO, PETITIONER

v.

AMERICAN PETROLEUM INSTITUTE, ET AL.

No. 78-1036

RAY MARSHALL, SECRETARY OF LABOR, PETITIONER

v.

AMERICAN PETROLEUM INSTITUTE, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF FOR THE FEDERAL PARTIES

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-33a)[1] is reported at 581 F.2d 493. The regulation

[1] We use the following abbreviations in this brief. "Pet. App." refers to the separate appendix to the petition in No. 78-911. "A." refers to the Joint Appendix filed in this Court. "Tr." refers to the transcript of the rulemaking hearings

in question and the Secretary's accompanying explanation (Pet. App. 34a-252a) appear at 43 Fed. Reg. 5918-5970.

JURISDICTION

The judgment of the court of appeals (Pet. App. 254a-255a) was entered on October 5, 1978 (A. 37). The petition for a writ of certiorari in No. 78-911 was filed on December 7, 1978, and the petition in No. 78-1036 on December 26, 1978. The petitions were granted and the cases consolidated on February 21, 1979 (A. 38-39). The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

QUESTIONS PRESENTED

1. Whether a health and safety standard for a toxic substance promulgated by the Secretary of Labor pursuant to 29 U.S.C. 655(b) must satisfy a cost-benefit test.

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conducted in 1977 prior to the final standard. "Exh." refers to exhibits received during the rulemaking proceeding. "Amend. Tr." refers to the transcript of the hearings in May 1977 on the amendment to the standard. (For the Court's convenience, an index to the voluminous record has been prepared by the parties and will be lodged with the Clerk.) "Leg. Hist." references are to the Subcomm. on Labor of the Senate Comm. on Labor and Public Welfare, 92d Cong., 1st Sess., Legislative History of the Occupational Safety and Health Act of 1970 (Comm. Print 1971). The Act confers the rulemaking power at issue on the Secretary of Labor, who, in turn, has delegated it to the Assistant Secretary of Labor for Occupational Safety and Health. For convenience, we shall refer to the Secretary, the Assistant Secretary, and the Occupational Safety and Health Administration as "the Secretary."

2. Whether a health and safety standard that is supported by substantial evidence based on the best available scientific knowledge may be set aside because of the possibility that future scientific studies will provide better evidence concerning the need for the standard.

STATUTE INVOLVED

Section 3(8) of the Occupational Safety and Health Act of 1970, 29 U.S.C. 652(8), provides:

> The term "occupational safety and health standard" means a standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment.

Section 6(b)(5) of the Act, 29 U.S.C. 655(b)(5), provides:

> The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In ad-

dition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws.

STATEMENT

On February 10, 1978, the Secretary of Labor promulgated an occupational health standard restricting employee exposure to benzene. The standard (1) sets a maximum permissible exposure level (PEL) in the workplace of 1 part per million (ppm) of airborne benzene, averaged over an eight-hour period with a ceiling exposure for a 15-minute period of 5 ppm; (2) requires engineering and work practice controls as the primary means to achieve this level; and (3) where employees are exposed to liquids containing benzene, requires the use of protective equipment to prevent skin and eye contact with liquid benzene. The court of appeals set aside the first two aspects of the standard because, in the court's view, the requirements are not "reasonably necessary" to provide healthful employment within the meaning of Section 652(8). The court set aside the protective clothing requirement because it concluded that the requirement is not based on the "latest available scientific data in the field" within the meaning of Section 655(b)(5).

A. The Occupational Safety and Health Act [2]

Congress enacted the Occupational Safety and Health Act of 1970 (OSHA) "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions." 29 U.S.C. 651(b). See generally *Atlas Roofing Co.* v. *OSHRC*, 430 U.S. 442, 444-445 (1977).

The Act imposes two duties on employers. One is a "general duty" to furnish employment and a place of employment "free from recognized hazards that are causing or are likely to cause death or serious physical harm * * *." 29 U.S.C. 654(a)(1). Employers also must obey "occupational safety and health standards" set by the Secretary of Labor. 29 U.S.C. 654(a)(2). These are standards "which require[] conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment." 29 U.S.C. 652(8).

The Act authorizes the Secretary to issue three types of standards. During the first two years of the Act, 29 U.S.C. 655(a) permitted the Secretary to adopt as an occupational health or safety standard any preexisting "national consensus standard" or

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[2] This Court has reviewed the OSHA enforcement scheme in the light of constitutional challenges raised under the Fourth and Seventh Amendments. *Marshall* v. *Barlow's, Inc.*, 436 U.S. 307 (1978); *Atlas Roofing Co.* v. *OSHRC*, 430 U.S. 442 (1977). This case is the first occasion for the Court to consider the scope of the Secretary's statutory power to set occupational health and safety standards.

"established Federal standard." 29 U.S.C. 655(a).[3] In the event that there was more than one such standard, the Secretary was required to select the standard that assured "the greatest protection of the safety or health of the affected employees." 29 U.S.C. 655(a). Several thousand such standards are in force; they are the great bulk of OSHA standards.

The second kind of standard is the "emergency temporary standard," which the Secretary may issue to take immediate effect when he determines that employees are exposed to grave danger from toxic materials or harmful physical agents and concludes

[3] A "national consensus standard" is any occupational safety or health standard that "(1) has been adopted and promulgated by a nationally recognized standards-producing organization under procedures whereby it can be determined by the Secretary that persons interested and affected by the scope or provisions of the standard have reached substantial agreement on its adoption, (2) was formulated in a manner which afforded an opportunity for diverse views to be considered and (3) has been designated as such a standard by the Secretary, after consultation with other appropriate Federal agencies." 29 U.S.C. 652(9). The term "established Federal standard" means any "operative occupational health and safety standard established by any agency of the United States * * *." 29 U.S.C. 652(10). As a result of this provision and 29 U.S.C. 653(b)(2), a number of standards issued under other statutes—including the Walsh-Healey Act, 41 U.S.C. 35-45; the Service Contract Act of 1965, 41 U.S.C. 351-357; the Contract Work Hours and Safety Standards Act, 40 U.S.C. 327-333; the Longshoremen's and Harbor Workers' Compensation Act, 33 U.S.C. 901-950; and the National Foundation on Arts and Humanities Act, 20 U.S.C. 951-960—became occupational health and safety standards under OSHA. The standards issued under other statutes were adopted without the need for repromulgation.

that such emergency standards are necessary to protect employees. 29 U.S.C. 655(c).[4]

The third type of standard is the permanent standard. 29 U.S.C. 655(b) prescribes a rulemaking procedure for fashioning permanent standards to supersede standards previously adopted under Section 655(a) or to provide new standards where none previously existed. Section 655(b) generally permits the Secretary to set whatever standard he determines is appropriate for health or safety protection.[5] Where, however, the Secretary sets a permanent standard for toxic materials or harmful physical agents, Section 655(b)(5) requires the Secretary to

> set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development

[4] Emergency temporary standards may remain effective no more than six months. 29 U.S.C. 655(c)(3).

[5] The Secretary must determine "that a rule should be promulgated in order to serve the objectives of the [Act]," 29 U.S.C. 655(b)(1), and must give "due regard to the urgency of the need for mandatory safety and health standards for particular industries" and to the "recommendations of the Secretary of Health, Education, and Welfare * * *." 29 U.S.C. 655(g). Whenever a permanent standard "differs substantially from" a national consensus standard, the Secretary must explain "why the rule as adopted will better effectuate the purposes of" the Act. 29 U.S.C. 655(b)(8).

> of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws.

The Act establishes a National Institute for Occupational Safety and Health (NIOSH) to assist the Secretary in his tasks.[6] The standards adopted by the Secretary, including toxic-substances standards, may permit variances in certain circumstances, but economic hardship is not a ground for a variance.[7]

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[6] NIOSH is required, on the basis of research, demonstrations and experiments, to "develop criteria dealing with toxic materials and harmful physical agents and substances which will describe exposure levels that are safe for various periods of employment, including but not limited to the exposure levels at which no employee will suffer impaired health or functional capacities or diminished life expectancy as a result of his work experience." 29 U.S.C. 669(a)(3). (NIOSH performs this duty as the Secretary's delegate. 29 U.S.C. 671(a).) NIOSH is to publish annually a list of all known toxic substances by generic family or other useful grouping, and the concentrations at which such toxicity is known to occur. If a potentially toxic substance is not covered by any standard, NIOSH must so advise the Secretary. 29 U.S.C. 669(a)(6) and (e).

[7] Any employer may apply to the Secretary for a "temporary" variance where, among other things, he is unable to comply because the necessary construction or alteration of facilities cannot be completed by the effective date of the standard. 29 U.S.C. 655(b)(6)(A). An employer is entitled to a "permanent" variance if he establishes that the conditions, practices, means, methods, operations, or processes used or proposed to be used by it will provide employment and places of employment as safe and healthful as those that would prevail if it complied with the standard. 29 U.S.C. 655(d). Thus, the statute is "cost-effective" in the sense that it permits employers to meet the performance standards in any way that provides the designated level of protection. Although economic hardship may not be a ground for a temporary variance (see Leg. Hist. 1188, 1201), the Act provides for small business loans to finance the cost of compliance. 15 U.S.C. 636.

Section 655(f) authorizes pre-enforcement review of a new standard by the court of appeals at the request of any person adversely affected by the standard. Petitions for review must be filed, if at all, within 60 days after promulgation of the standard. In such proceedings "[t]he determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole." 29 U.S.C. 655(f).

B. Previous Benzene Standards

Benzene[8] has long been known to cause a number of nonmalignant blood diseases, some fatal. See pages

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[8] Benzene is a clear, colorless, noncorrosive, highly flammable hydrocarbon (C_6H_6) with a strong, rather pleasant odor. Benzene's low boiling point and high vapor pressure cause it to evaporate rapidly under ordinary atmospheric conditions (Pet. App. 69a). Benzene can be present naturally in small quantities (a few parts per billion). It is manufactured in substantial quantities for a wide variety of industrial uses (*id.* at 69a-70a). It is used as a solvent and in the manufacture of other organic chemicals, pesticides, detergents, solvents and paint removers. Industries currently using benzene include the chemical, petroleum, rubber fabricating, adhesive, varnish and paint industries (*id.* at 70a). The petrochemical and petroleum refining industries produce 94% of the total domestic production of benzene (*id.* at 69a). Recovery of

15-20, *infra*. More recently, it has been determined that benzene causes leukemia.

For many decades before benzene's carcinogenic effects were established, groups responsible for recommending levels of exposure to benzene had reduced the recommended levels again and again.[9] In 1971, shortly after the Act was passed, the Secretary adopted a preexisting national consensus standard for benzene under the authority of Section 655(a). See 29 C.F.R. 1910.1000, Table Z-2 (1977). That standard allowed an eight-hour time-weighted average (TWA) exposure of 10 ppm, with a maximum concentration of 25 ppm averaged over a 10-minute period. Concentration was not exceed 50 ppm at any time. This standard was based on benzene's known nonmalignant effects and not on any possible leukemia hazard (Pet. App. 71a; Exh. 2A-159 at 6-7).

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coal-derived benzene, primarily as a by-product of the coking process in steel mills, account for 6% of domestic production (*ibid.*). Only 11 other chemicals and one other hydrocarbon (ethylene) are produced in greater tonnage than benzene in this country (*ibid.*).

[9] See Pet. App. 71a. In 1946 the American Conference of Government Industrial Hygienists (ACGIH) recommended a threshold limit value (TLV) of 100 ppm. Its recommendation was reduced to 50 ppm in 1947. In 1948 it followed the Massachusetts Department of Occupational Hygiene in adopting a TLV of 35 ppm. In 1963 ACGIH once against reduced the recommended level, this time to 25 ppm. And in 1969 the American National Standards Institute, a voluntary standards-setting organization, adopted a TLV of 10 ppm. This reduction was based on the known hazards of benzene other than cancer. ACGIH reduced its recommended TLV to 10 ppm in 1974.

In 1974 NIOSH advised the Secretary that "the possibility that benzene can induce leukemia cannot be dismissed" (Exh. 2-3 at 75).[10] NIOSH observed, however, that the literature dealing with the effects of benzene on exposed workers consisted primarily of case history reports rather than statistically valid studies, and it concluded that there was no "conclusive" proof that exposure to benzene causes leukemia (Exh. 2-3 at 22-23, 40, 74-75). NIOSH therefore recommended no changes in the current standard's TWA of 10 ppm. On the basis of benzene's nonmalignant effects, however, NIOSH recommended that the ceiling of exposure to benzene for a 15-minute period be reduced to 25 ppm, and that increased monitoring, medical surveillance and labeling requirements be imposed (Pet. App. 72a).

Between 1974 and 1976 several epidemiological studies[11] demonstrated a statistically significant risk that workers occupationally exposed to benzene would develop leukemia. In 1976 the National Research Council reviewed the available data and concluded that benzene must be considered a carcinogen (Exh.

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[10] NIOSH's report can be found at 42 Fed. Reg. 22516 (1977).

[11] In an epidemiological investigation, scientists select a group ("cohort") of workers who have received exposure to a chemical for a number of years. They then compare the number of cancers in that group with the number of cancers in a similar group that has not been exposed to the chemical, in order to determine if exposure to that chemical is associated with the formation of cancers.

2-4 at iii).[12] In 1976 NIOSH reported to the Secretary that the accumulated clinical and epidemiological studies conclusively established that benzene causes leukemia (Exh. 2-5 at 10). NIOSH stated that it could not ascertain a "safe" level for benzene exposure (*ibid.*), and it recommended that permissible exposure be lowered to a two-hour TWA of 1 ppm in the air (Pet. App. 72a). Shortly thereafter, NIOSH "strongly recommend[ed]" that the Secretary immediately promulgate an emergency temporary standard (Pet. App. 72a; Exh. 2-6 at 1).

In January 1977 the Secretary issued voluntary "Guidelines for Control of Occupational Exposure to Benzene." These guidelines recommended that exposure not exceed 1 ppm (Pet. App. 73a; Exh. 2-44). In April 1977 NIOSH released to the Secretary the preliminary results of another study showing a risk of leukemia among workers exposed to benzene and again urged him to issue an emergency temporary standard. On May 3, 1977, the Secretary issued an emergency standard, which set a maximum exposure limit of 1 ppm. 42 Fed. Reg. 22516 (1977).[13]

[12] The National Research Council is the principal operating agency of the National Academy of Sciences, a congressionally chartered, quasi-official organization of distinguished scientists and technologists which investigates and reports upon broad scientific problems relevant to the public welfare.

[13] Several petitions for review were filed. See *Industrial Union, AFL-CIO* v. *Bingham*, No. 77-1395 (D.C. Cir.); *American Petroleum Institute* v. *OSHA*, No. 77-1516 (5th Cir.). The Fifth Circuit stayed the emergency temporary standard. No decision on the merits was issued by either court. The emergency temporary standard was never enforced.

C. The Permanent Standard

On May 27, 1977, the Secretary published a proposed permanent standard for benzene. 42 Fed. Reg. 27452 (1977). The proposed standard established an exposure limit of 1 ppm averaged over an eight-hour period, with a ceiling of 5 ppm during any 15-minute period. The proposal also required the use of gloves, masks, or other apparel to prevent eye contact with benzene and repeated or prolonged skin exposure to liquid benzene. In addition, monitoring of airborne concentrations of benzene, medical surveillance, labeling, and recordkeeping were proposed (*id.* at 22521-22522, 27454). The agency proposed to exempt work operations during the first year of the standard where the only exposure to benzene was from liquid mixtures containing 1% or less benzene. After the first year, the exception was to apply only to liquids containing 0.1% or less benzene (*id.* at 27460-27461).[14] Public comment on the proposal was invited (*id.* at 27452).

The agency received extensive comments from numerous parties, and a hearing was conducted from July 19 through August 10, 1977. Ninety-five persons appeared as witnesses to represent industries including refining, petrochemical, oil and gas production, aviation fueling, and coke ovens and coke

[14] The proposal also excluded activities related to storage, distribution, and sale of gasoline as a fuel subsequent to its discharge from bulk terminals. The agency explained that this area was the subject of an ongoing study and that it intended to assess the situation after conclusion of that study (42 Fed. Reg. 27453 (1977)).

by-products. Comments were received from representatives of other industries, such as analytical and research laboratories, paint manufacturing, construction, maritime, and rubber manufacturing. Representatives of the affected workforce, including a number of employees who had been exposed to benzene, also testified (Pet. App. 74a-75a). The record of this proceeding includes a hearing transcript of 3,500 pages and more than 1,100 comments and exhibits.

On February 10, 1978, the Secretary issued the permanent standard (Pet. App. 34a-66a).[15] The standard, codified at 29 C.F.R. 1910.1028, requires that occupational exposure to airborne benzene be reduced so that no employee is exposed to more than 1 ppm of benzene in the air, averaged over eight hours, or to more than 5 ppm of airborne benzene averaged over 15 minutes. Section 1910.1028 (c)(1). The standard requires monitoring of exposure levels and requires employers to advise employees of their exposure levels. Section 1910.1028 (c). Employers must implement engineering controls and work practices to bring exposures within permissible limits or as low as possible, and until they do so must require employees to wear respirators. Section 1910.1028(f). The standard also requires labeling of products containing benzene (Section 1910.1028(k)), medical surveillance (Section 1910.-

[15] 43 Fed. Reg. 5917-5970 (1978). Errata appear at 43 Fed. Reg. 13561-13563 (1978). The printed appendix to the petition in No. 78-911 does not contain the corrections, which we will note as necessary.

1028(i)), and employee training (Section 1910.1028 (j)). Direct skin and eye contact with liquids containing benzene is prohibited, and protective clothing must be provided to employees who are likely to be exposed to such liquids (Section 1910.1028(c)(2) and (h)).

D. The Basis for the Standard

The Secretary issued a lengthy statement of findings and conclusions based on the administrative record, explaining why he adopted the standard (Pet. App. 67a-251a).

1. *Toxic effects of benzene*

The Secretary concluded that the evidence in the record conclusively establishes that benzene causes leukemia, a cancer of the white blood cells that causes rapid death (*id.* at 98a-99a, 122a).[16] The Secretary summarized the voluminous evidence and studies linking benzene with leukemia (*id.* at 99a-132a). One study, for example, showed that workers exposed to benzene had a risk of leukemia 20 times greater than the normal population (*id.* at 100a); another study showed a risk five times greater (*id.* at 105a).[17] In-

[16] Despite the fact that half of the adults diagnosed with the subtype of leukemia (acute myelogenous leukemia or AML) most commonly associated with benzene have remissions averaging from six to eight months, the prognosis of the disease remains poor. Those who enter into remission have life expectancies of 12 to 18 months; those who do not generally die within three to six months (Pet. App. 99a).

[17] In 1977 Dr. Peter F. Infante of NIOSH reported the results of his retrospective epidemiological study of leukemia

dustry participants in the hearing did not, for the most part, challenge the conclusion that benzene causes leukemia (Pet. App. 123a). They argued, however, that a threshold existed below which exposure to benzene was safe and that 10 ppm, the

among benzene-exposed workers employed at Goodyear's Akron and St. Mary's plants between 1940 and 1949 (Exhs. 2-51, 2A-271). Causes of death among these workers were determined from death certificates. Dr. Infante and his colleagues reported that this study showed a statistically significant five-fold increased risk of dying of leukemia, and a 10-fold increased risk of dying of the type of leukemia (AML) most commonly associated with benzene, when compared to two control groups.

Dr. Infante made several assumptions that tend to underestimate the cancer risk. First, the status of a number of employees could not be determined. They were assumed to be alive. Second, Dr. Infante relied on death certificates to determine the cause of death; these tend to understate the incidence of leukemia. Third, Dr. Infante excluded deaths before 1950. Some victims may have died in the period 1940-1949 (see Exh. 2-51).

Dr. Marvin Sakol, a hematologist, testified that he had observed nine leukemia cases among the workers studied by Dr. Infante, almost twice the number reported in the Infante study (Tr. 286-289, 307, 308-315; Exh. 61). He also observed 12 new leukemia cases between 1960 and 1973; at least five of these had worked at the plant studied by Dr. Infante (Tr. 315-316). He testified that during the 1950s, when workers' compensation programs did not recognize leukemia as a compensable employment-related disease, physicians would sign death certificates stating that the cause of death was aplastic anemia, rather than a diagnosed leukemia, so the family would receive compensation (Tr. 311). Dr. Sakol also testified that the use of death certificates to find the causes of death leads to underestimation of the number of cases because the immediate cause of death of leukemia patients was often a resulting complication of the disease, such as a heart attack (Tr. 307-308).

existing standard, was within the safe range (*id.* at 123a-124a). This argument was based chiefly on "negative" epidemiological studies of certain groups of employees, exposed to low levels of benzene, who did not contract leukemia. The thresholds were said to lie between the exposure levels of these studies and the higher exposure levels at which cancers have been shown to occur.

Although the issue whether thresholds exist is argued "in a manner similar to those arguing religion" (Exh. 217.32.H.16 at 1), the majority of the cancer specialists at the hearing testified that there are no data reliably establishing that a safe level exists for benzene.[18] The Secretary concluded that no threshold for benzene could be found because (i) given difficulties in methods, negative studies are generally less informative than positive ones (see Pet. App. 123a-124a), and the specific negative studies presented by the industrial parties, each of which the

[18] See the testimony of Dr. Robert N. Ligo of NIOSH (Tr. 1225; Dr. Herman F. Kraybill of the National Cancer Institute (Tr. 775-778, 1178-1180, 1210); Dr. Charles Shaw of NIOSH (Tr. 401-402); Dr. Peter Infante of NIOSH (Tr. 1066); Dr. John A. Zapp, Jr., testifying for the Manufacturing Chemists Association (MCA) (Exh. 149-D at 15); Dr. Bernard Goldstein of the New York University Medical Center (Tr. 352); Dr. Leonard J. Goldwater, testifying for the MCA (Tr. 2500, 2520-2521); Dr. William R. Gaffey, testifying for respondent American Petroleum Institute (Tr. 1372). This testimony was consistent with the 1970 report of the National Cancer Institute's (NCI's) Ad Hoc Committee on the Evaluation of Low Levels of Environmental Carcinogens, which states: "for carcinogenic agents a 'safe level for man' cannot be established by application of our present knowledge" (Exh. 2.B.272 at 1). NCI reaffirmed this view at the rulemaking hearing (Tr. 1178-1179).

Secretary discussed, are defective;[19] (ii) the available data concerning workers exposed to benzene do not show the levels of exposure, and it is therefore impossible to construct a risk-assessment (or dose-response) curve that would plot the risk of cancer as a function of the degree of exposure;[20] and (iii) the biological mechanism by which benzene causes leukemia is not known (Tr. 363; Exh. 217.32.H.26 at 25).

The existence of a risk of cancer even at levels of exposure lower than 10 ppm also was supported by the three affirmative considerations. First, many physicians subscribe to the theory that "all it takes to start the carcinogenic process is to have one molecule of the carcinogen hit the proper site that they now have identified as DNA in the nucleus of the susceptible organ site" (Exh. 97 at 55). If this theory is correct, there is an ever-present risk of cancer at any exposure, although the risk decreases as the exposure level decreases and increases with the duration of the exposure. Second, there is known to be great variation in the degree of susceptibility of persons to benzene's leukemogenic effects, suggesting that the biological mechanism by which benzene causes cancer is influenced by age, prior medical problems, genetic factors, exposure to other carcinogens, and other variables (Pet. App. 117a-118a). Thus, even if certain employees would be safe at certain levels of exposure, other employees might not be safe. The more susceptible employees cannot be identified in advance of exposure (*id.* at 184a). Third, even if a high level of exposure is necessary to induce leukemia where the duration of exposure is short, repeated or continual exposures to low concentrations may be equally sufficient to cause leukemia (Pet. App. 116a-117a; Tr. 420, 3209).[21]

The Secretary also concluded that benzene causes nonmalignant blood diseases, some fatal, for which no level of safety was known (Pet. App. 96a-98a),[22]

[19] For example, some of the studies did not separate workers who were exposed to benzene from those who were not in computing the study population's risk of leukemia. Others failed to perform follow-up investigations of workers once they had left the plant, thereby excluding two groups who regularly have a statistically higher incidence of disease than active workers—retirees and people who terminate employment early. Still others failed to indicate information necessary to permit any evaluation of their validity, such as how the study population was chosen and how long workers had been exposed to benzene (see Pet. App. 107a-112a).

[20] See pages 62-69, *infra*.

[21] The mathematical techniques that have been suggested for computing thresholds give extraordinarily low figures. For example, Dr. Leonard J. Goldwater calculated that the threshold for vinyl chloride is .03 parts per billion (Tr. 2524-2526). Similarly, Dr. Herman F. Kraybill testified that scientists are generally suggesting that "10^3 molecules, 10^6 or 10^9" could induce cancer (Tr. 1179). An employee exposed at 1 ppm would inhale far more than 10^9 molecules of benzene in an hour. (The Secretary, however, believes that these techniques do not yield reliable estimates of the risk of cancer.)

[22] Benzene reduces the number of red blood cells, white blood cells and platelets (*id.* at 82a). A decline of all three is known as aplastic anemia, which may be fatal (*id.* at 82a-84a). Decline in the number of red blood cells leads to anemia which, if chronic, may lead to exacerbation of coronary insufficiencies or other heart conditions (*ibid.*). A decline in the number of white blood cells reduces the natural immunity of the body

and caused chromosomal damage.[23] These hazards, he concluded, independently called for reductions in exposure (*id.* at 97a-98a).

2. *The policy of the lowest feasible level of exposure*

Had the Secretary found a safe and achievable level of exposure to benzene, he would have set the standard at that level (Pet. App. 183a-190a). Having found no safe level of exposure to benzene, the Secretary was required to decide how stringent the standard should be. He considered two kinds of approach to this task.

One body of public health opinion holds that, where a safe level of exposure to a carcinogen is not known, exposure should be kept at zero or, if that is not

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from disease (*ibid.*). Loss of platelets impairs clotting and may lead to hemorrhages (*id.* at 82a-83a). Some nonmalignant blood disorders of employees exposed to benzene have been fatal (*id.* at 89a). The record shows instances of blood abnormalities from exposure in the 25-40 ppm range and aplastic anemia from exposures as low as 5-10 ppm (*id.* at 89a; Exhs. 154 (Ott Study), 159A, 2B-304). Dermal contact with liquid benzene may cause erythema, blistering, dermatitis and secondary dermal infections (Pet. App. 80a).

[23] See Pet. App. 126a-132a. Several studies show chromosomal damages below 25 ppm, perhaps as low as 10 ppm (*id.* at 128a; Exh. 5B at 3-3). It has been suggested that the chromosomal damage is associated with leukemia or may result in genetic mutations (Exhs. 2-94, 2-102, 132). It is not now possible to determine conclusively what these chromosomal aberrations mean in terms of demonstrable health effects. The Secretary noted, however, that "chromosomal damage represents an adverse biological event of serious concern which may pose or reflect a potential health risk and as such, must be considered in the larger purview of adverse health effects associated with benzene" (Pet. App. 132a).

possible, at the lowest feasible level (Pet. App. 183a-190a). Considerable medical and public health opinion supports this policy (Tr. 148-149, 328, 351, 1229, 1999-2000; Exhs. 2.B.272 at 1-2, 2-5 at 10). In view of the command of 29 U.S.C. 655(b)(5) that the Secretary adopt "the" standard that "most adequately assures, to the extent feasible" that "no" employee will suffer material health impairment even if he is exposed for his entire working life, the Secretary adopted this approach, as he has in promulgating numerous other OSHA standards for carcinogens.[24] The Secretary found that the lowest feasible level is 1 ppm (Pet. App. 187a).[25]

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[24] In setting standards for carcinogens and other toxic materials for which no known safe level of exposure can be found, the Secretary has consistently adopted the lowest feasible level and expressly declined to implement a cost-benefit approach. See 37 Fed. Reg. 11318 (1972) (asbestos dust); 39 Fed. Reg. 3756, 3758 (1974) (14 substances); 39 Fed. Reg. 35890, 35892 (1974) (vinyl chloride); 41 Fed. Reg. 46742, 46750-46751 (1976) (coke oven emissions); 43 Fed. Reg. 27360, 27378-27379 (1978) (cotton dust); 43 Fed. Reg. 52952, 52963 (1978) (lead dust); 43 Fed. Reg. 45762, 45790 (1978) (acrylonitrile).

The Secretary also has published a proposed regulation that would permit him to establish categories of toxic substances. See 42 Fed. Reg. 54148 (1977) (Identification, Classification and Regulation of Toxic Substances Posing a Potential Carcinogenic Risk).

[25] The Secretary also found that prudent public health policy would lead to the 1 ppm level without regard to benzene's causation of leukemia. After observing that benzene was known to cause blood diseases at exposures less than 100 ppm, the Secretary observed (*id.* at 97a-98a):

> It is customary to use a safety factor of 10-100 or greater depending on the seriousness of the toxic effects and the

Industry witnesses suggested a different approach (see A. 40-58, 77-94, 135-148, 158-179). They contended that the degree of health protection should be determined through a cost-benefit technique, which would measure as closely as possible the number of lives that would be saved at progressively lower levels of exposure. Under this approach the Secretary would set the level of exposure at the point where the additional lives saved by further reduction are not worth the additional cost to save them (Pet. App. 160a-161a). Whether the cost is worthwhile would be determined by comparing the estimate of the number of lives that would be saved by the new standard with the number of lives (and other health or environmental benefits) that might be achieved by requiring industry to apply the same funds to meet other environmental or health standards. At a minimum, industry argued, workers ought to be willing to tolerate health risks comparable to those government has, in other contexts, implicitly found to be "acceptable."

The Council on Wage and Price Stability, in a somewhat similar fashion, urged OSHA to investigate the incremental costs and benefits of alternative standards "to determine whether a proposed standard should be made even more stringent or perhaps re-

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nature of the data being relied upon. That is, the lowest levels at which effects had been observed would be reduced by the safety factor chosen in establishing the exposure limit. Taking this approach in the case of benzene would lead to a permissible exposure substantially less than 10 ppm without regard to the issue of leukemia and the view that no safe level can be established for the carcinogenic risk.

laxed in some circumstances" (A. 131). The Council concluded that, although the procedures it suggested to estimate the health impact of alternative benzene standards would not "yield an accurate calculation of incremental benefits, they would provide a range of health benefit estimates that should be included in an economic analysis in order to aid OSHA in setting the final standard" (A. 130).

The Secretary explained his decision not to adopt these approaches on two grounds. First, the Secretary concluded that the lack of data made it impossible to quantify the health risk at various levels of exposure, and prudent public health policy required that exposure to a known carcinogen be reduced as much as possible until such time as it can be shown that a safe threshold of exposure exists (*id.* at 160a). Second, even if data were available to quantify the risk, Section 655(b)(5) requires the adoption of the standard which assures maximum benefit (*i.e.*, prevention of serious illness or death), constrained only by the limits of feasibility (Pet. App. 162a):

> In making judgments about specific hazards, OSHA is given discretion which is essentially legislative in nature. However, in setting an exposure limit for a substance like benzene, OSHA may not substitute cost benefit criteria for the legislatively determined directive of protecting all exposed employees against material impairment of health or bodily function. Where the health effectiveness of the alternative approaches are extremely uncertain and likely to vary from situation to situation, OSHA must adopt the compliance strategy which provides

the greatest certainty of worker protection even if that approach carries with it greater economic burdens for the affected employers. In the case of the benzene standard, the evidence in the record indicates that the costs of compliance are not overly burdensome to industry.[26]

[26] Although the Secretary disclaimed any obligation to quantify the health benefits and standards, in response to the contention that standards should be set by weighing health benefits against costs the Secretary stated (Pet. App. 160a):

> There is general agreement that benzene exposure causes leukemia as well as other fatal diseases of the bloodforming organs. In spite of the certainty of this conclusion, there does not exist an adequate scientific basis for establishing the quantitative dose response relationship between exposure to benzene and the induction of leukemia and other blood diseases. The uncertainty in both the actual magnitude of expected deaths and in the theory of extrapolation from existing data to the OSHA exposure levels places the estimation of benefits on "the frontiers of scientific knowledge." While the actual estimation of the number of cancers to be prevented is highly uncertain, the evidence indicates that the number may be appreciable. There is general agreement that even in the absence of the ability to establish a "threshold" or "safe" level for benzene and other carcinogens, a dose response relationship is likely to exist; that is, exposure to higher doses carries with it a higher risk of cancer, and conversely, exposure to lower levels is accompanied by a reduced risk, even though a precise quantitative relationship cannot be established. In light of the uncertainties in this area of scientific knowledge, OSHA believes that it is required by prudence and by the statutory mandate to adopt a highly protective posture in considering the evidence for health benefits.

The Secretary found that 629,000 employees are affected by the benzene standard and that at least 30,000 employees are exposed now to levels between 1 ppm and 10 ppm (see Pet. App. 141a-155a).

3. *Feasibility*

The Secretary recognized that standards set under Section 655(b)(5) must be "feasible" (Pet. App. 132a-133a). To assess the economic feasibility of the proposed standard, the agency commissioned Arthur D. Little, Inc., to study the economic effect of the proposed standard on the affected industries. The Secretary thoroughly reviewed the Little study (*id.* at 134a-158a).

The Little study considered compliance costs with respect to each of 20 affected industries (Pet. App. 142a-153a). It concluded that the aggregate first-year operating costs would be in the range of $187 million to $205 million. Recurring annual costs thereafter were estimated at approximately $34 million. One-time investment in engineering controls was estimated at approximately $266 million (*id.* at 134a). After comparing these costs with information on the profitability and capitalization of the affected industries, the Secretary concluded that there is no "serious question concerning the economic feasibility of the standard or the ability of the regulated industries to bear the additional costs" and that the compliance costs are "well within the financial capability of the covered industries" (*id.* at 135a, 163a).

4. *Protective clothing*

The proposed and final standard prohibited all eye and skin contact with certain liquids containing benzene and required protective clothing where employees may have repeated eye or skin contact with such liquids (Section 1910.1028(h), 42 Fed. Reg. 27461 (1977); Section 1910.1028(c)(2), and (h), Pet. App.

36a, 42a). This requirement is based on the Secretary's policy, consistent with recognized industrial hygiene practice, that "in dealing with a carcinogen, all potential routes of exposure (i.e. inhalation, ingestion, and skin absorption) be limited to the extent feasible" (*id.* at 192a).

During the hearings, Dr. Howard Maibach testified on behalf of respondent American Petroleum Institute (Tr. 2459; A. 58) that, although he had no personal information about whether benzene may be absorbed through the skin, the extent of absorption (including the effect on absorption of temperature, solution strength, repeated application, *etc.*) could be resolved conclusively by conducting tests on animals using Carbon-14 (Tr. 2459-2490; A. 58-77, 149-157).[27] "[W]ith modern analytic and biological technology," he stated, "it should be very simple, very quickly, and inexpensively to answer this" (Tr. 2467; A. 63). He stated that the tests could be conducted in six to twelve weeks (Tr. 2487; A. 75) and at one point testified that "in the six weeks necessary to do these experiments, you will have your answer" (Tr. 2488; A. 76). Dr. Maibach did not say that he was conducting such tests or that he intended to do so. Although the hearing record was held open until September 2, 1977, neither Dr. Maibach nor anyone else submitted the results of any such experiment.

[27] The test involves applying radioactive benzene solution to animal skin and later measuring the amount of radioactive benzene in the animal's feces and urine to determine how much of the benzene had penetrated the skin.

The Secretary concluded that five considerations supported the view that dermal contact should be prohibited. First, "the view is generally accepted that [benzene] has the ability to be absorbed through the skin * * *" (Exh. 2-69 at 1; A. 107, 119-120; Tr. 860; A. 40; see Pet. App. 193a).[28] Physicians believe that benzene is absorbed because benzene is a powerful lipid solvent—a characteristic which indicates it can break through the protective cutaneous barrier (Exh. 2: A-187 at 11). Experiments show skin absorption of benzene in animals (Exhs. 2-31 at 12, 2-46 at 1-2; A. 95-96; Exh. 2-69 at 1-2; A. 107-108) and in humans (Exh. 2-69; A. 119-120).[29]

Second, even if benzene were not absorbed through intact skin, it may be absorbed through damaged skin (Pet. App. 193a). As Dr. Maibach testified, scientific experts "ordinarily assumed that penetration of any molecule will be greater through damaged skin than undamaged skin" (Tr. 2469-2470; A. 64-65). Benzene itself can damage the outermost protective cutaneous layer (see Exhs. 2-3 at 5, 53; 2-48;

[28] See also Exhs. 2-31 at 12; 2-48; 2:A.187 at 11.

[29] The Secretary did not consider these studies to be definitive, either because of their lack of control data or because of their failure to consider factors that the scientific community has found to be relevant to the permeability of human skin (Pet. App. 193a; see Tr. 2463-2464; A. 60-61). On the other hand, studies indicating that benzene is not absorbed in humans (Exhs. 2-46, 2-47; A. 95-106; Tr. 2462-2463; A. 59-60) were not considered sufficient because they are based on analysis of the sulfate ratio in the subjects' urine, a factor too insensitive and non-specific for useful application (Exhs. 2-69 at 3; A. 109; 2:A-112 at 3; Tr. 2462-2463; A. 59-60).

2:A-111 at 9; 2:A-112 at 2; 2:A-187 at 6, 11), thus increasing the likelihood of absorption.

Third, benzene often is added to or present as a contaminant in industrial solvents containing other chemically-related substances. See Exh. 5A at 4-19, 4-27 to 4-28, 4-31 to 4-32. Some of these chemically-related substances, such as xylene and toluene, are readily absorbed through the skin (see Exh. 2-3 at 25). Such substances can act as "vehicles" or carriers, which result in or increase the extent of skin absorption of benzene (Pet. App. 194a).

Fourth, it is difficult to imagine a situation where dermal contact with benzene will not also result in airborne exposure to the vapors from that liquid. Thus, whatever exposure occurs via skin absorption simply adds to that from inhalation. It is therefore advisable to guard against dermal contact in order to prevent exposure in excess of the permissible safe exposure level set for ambient concentrations (Pet. App. 194a).

Finally, apart from the question of absorption, direct contact with liquids containing benzene can cause erythema and blistering (Pet. App. 80a). Prolonged or repeated skin contact with liquids containing benzene has been associated with the development of a dry, scaly dermatitis, and with secondary dermal infections (*ibid.*).

5. *The percentage exclusion*

The proposed standard exempted "work operations where the only exposure to benzene is from liquid

mixtures containing 1% (0.1% after one year from the effective date of this standard) or less of benzene by volume, or the vapors released from these liquids." Section 1910.1028(a)(2)(ii), 42 Fed. Reg. 27460 (1977). The exemption would have applied both to inhalation and to personal contact with liquids. The original announcement called for public comment on this proposed exclusion and suggested that the final standard might not contain any such exclusion.[30]

The standard promulgated on February 3, 1978, had no percentage exclusion. In response to contentions by industry that the standard was not technologically feasible without a percentage exclusion, and well after the petitions for review of the unamended standard were filed, the Secretary announced on March 28, 1978, proposed rulemaking to amend

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[30] The announcement stated (42 Fed. Reg. 27452 (1977)):

> One of the major issues involved in this proceeding is whether the final standard should exempt certain specified operations from its coverage. For the purpose of raising this issue, the proposal, as drafted, does not cover * * * operations in which the only exposure to benzene is from liquid mixtures which contain no more than 0.1% benzene (1% benzene during the first year after the effective date of the standard). The question of whether these types of operations should be exempted is raised herein, and some of the reasons for the suggested exclusion of these operations are set out below. If these operations are excluded from the final standard issued as a result of this rulemaking, they would still be covered by the existing benzene standard in § 1910.-1000. OSHA seeks public comment and evidence on these issues.

the standard to exclude certain liquids containing benzene. 43 Fed. Reg. 12890 (1978).

On May 27 and 28, 1978, the Secretary conducted hearings on the proposed percentage-exclusion amendment. During the hearing, counsel for respondent Rubber Manufacturers Association requested a 180-day stay of the standard, which had already been issued, while Dr. Maibach conducted tests on skin absorption (Amend. Tr. 15-23; A. 181-187). The Secretary replied that he would consider such a study but that he would not delay the standard while the study was being conducted (Amend. Tr. 20-21; A. 185-186).

On June 21, 1978, the Secretary announced a percentage exclusion almost identical to the one originally proposed. 43 Fed. Reg. 27971 (1978); A. 239-275.[31]

E. The Decision of the Court of Appeals

On petitions for review under 29 U.S.C. 655(f), the court of appeals set aside the standard.[32] The

[31] The original proposal would have exempted work operations where the only exposure is from liquids containing 1% or less benzene during the first year and 0.1% thereafter. Section 1910.1028(a)(2)(ii), 42 Fed. Reg. 27460 (1977). The final amended standard exempted work operations where the only exposure is from liquids containing 0.5% or less benzene by volume during the first *three* years of the standard and 0.1% thereafter. Section 1910.1028(a)(2)(iii); A. 275.

[32] The initial petition for review was filed in the Fifth Circuit by respondent American Petroleum Institute. Petitions subsequently filed in other circuits were transferred to the Fifth Circuit and consolidated for review (see A. 1-11). Other parties intervened in the Fifth Circuit.

The first petition for review was filed on February 2, 1978, well before the amendments to the standard had been promulgated (A. 12-13). The amendment was issued the day before oral argument. The court of appeals called for supplemental briefing on the effect of the amendment. It concluded that it did not need to review the amendment and reserved the question of its feasibility. Petitions for review of the amendment are still pending in the court of appeals. Because the alterations of the standard ultimately did not affect the court of appeals' disposition of the case, it is unnecessary to review the propriety of this procedure. Compare *Tagg Bros. & Moorhead* v. *United States*, 280 U.S. 420, 444-445 (1930), with *H & H Tire Co.* v. *United States Department of Transportation*, 471 F.2d 350, 353 n.10 (7th Cir. 1972).

court began by observing that Section 655(f) explicitly prescribes the standard of review: "The determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole." The court observed that there are both factual and policy determinations in rulemaking. Section 655(f) subjects factual determinations to the substantial evidence test (Pet. App. 5a). With respect to policy determinations by the Secretary, the court concluded, it need only determine whether "the Secretary exercised his decisionmaking power within the limits imposed by Congress" (*ibid.*).

Applying this standard, the court of appeals held that substantial evidence supports the Secretary's factual findings that (a) benzene causes cancer (Pet. App. 17a-18a); (b) benzene causes diseases, some fatal, other than cancer (*id.* at 7a); (c) exposure at the 10 ppm level poses a risk of leukemia (*id.* at 18a) and reduction of the level to 1 ppm would result in health benefits (*ibid.*). The court did not dis-

pute the Secretary's finding that the standard is economically and technologically feasible. The court acknowledged that it is not now possible to determine the relationship between exposure and risk (*id.* at 19a n.23).

The court nevertheless set aside the standard. It concluded that the Secretary must ascertain the number of lives (and other health benefits) that the standard will save and determine whether their value bears a "reasonable relationship" to the cost of implementing the standard (Pet. App. 19a-20a).[33] The court found this requirement in the Act's definition of an occupational health and safety standard, 29 U.S.C. 652(8), which defines such a standard to be one "which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, *reasonably necessary or appropate* to provide safe or healthful employment" (emphasis added). The court stated that this provision is analogous to a statutory requirement in the Consumer Product Safety Act that prohibits any consumer product safety rule unless the Consumer Product Safety Commission finds that the rule is "reasonably necessary to eliminate or reduce an unreasonable risk of injury associated with such

[33] The court of appeals stated that it did not require an "elaborate" cost-benefit analysis (Pet. App. 17a). Nonetheless, it did require the Secretary (1) to approximate the number of lives that the standard will save, and (2) to balance these benefits against the cost of the standard in determining the level of protection to accord employees (*id.* at 19a-22a). For convenience, we refer to these two requirements as a cost-benefit test.

product." 15 U.S.C. 2058(c)(2)(A). Having held in *Aqua Slide 'N' Dive Corp.* v. *CPSC*, 569 F.2d 831, 842 (5th Cir. 1978), that the latter provision requires the agency to find that the benefits of its rule bear a reasonable relationship to the costs, the court "decline[d] to construe the precisely similar requirements of these two acts differently or to read words out of the OSHA legislation" (Pet. App. 14a-15a).

To the Secretary's argument that 29 U.S.C. 655(b)(5) calls for the "highest degree of health and safety protection" and requires the selection of the standard that "most adequately assures, to the extent feasible" that no employee will suffer material impairment of health even if he is exposed for his entire working career, the court responded that the Secretary is not given "unbridled discretion" to create "absolutely risk-free workplaces regardless of cost" (Pet. App. 15a). The statute limits the Secretary to "feasible" standards based on "the best available evidence." These provisions suggested to the court "pragmatic limitations" on the Secretary's decisions (*id.* at 16a). In any event, the court thought, in view of the parallel purposes of OSHA and the Consumer Product Safety Act it must be "guided by *Aqua Slide*" in determining whether the Secretary had chosen properly (*ibid.*).

The court held that the Secretary passed the "costs" part of its test by relying on the Little study to show that the cost of compliance was feasible (Pet. App. 17a). But the court stated that the Sec-

retary failed the "benefits" part of the test because he could not show that "measurable" benefits would result (*id.* at 18a). The court conceded that there is "general agreement in the scientific community that exposure to carcinogens at low levels is safer than exposure at higher levels" and that it is rational to conclude that a reduction in the limit from 10 to 1 ppm would result in "some benefit" (*ibid.*). As rational as this deduction might be, however, "mere rationality" was not sufficient. The Secretary must show "measurable benefits" (*ibid.*).[34]

The court acknowledged that the Secretary is unable to satisfy this requirement because the lack of data concerning the effects of exposure at low levels makes an estimate of benefits "impossible" (Pet. App. 19a n.23). Nonetheless, it concluded that the standard could not be upheld because "Congress provided that OSHA regulate on the basis of knowledge rather than on the unknown" (*id.* at 20a). The court speculated that the necessary data could be obtained in the future (*id.* at 19a n.23, 20a). (This speculation was based on three items of evidence that we discuss at note 56, *infra.*)

[34] Although disclaiming any obligation to satisfy a cost-benefit test, the Secretary argued that the standard would satisfy such a test because the standard is within the financial capability of the industry, because exposure to benzene is unsafe at any level, and because exposures to lower levels would be safer than exposures at higher levels. Conceding that "some" health benefits would result from the lower standard, the court nonetheless rejected this argument, holding that "some" benefits did not satisfy its test, which requires benefits to be quantified (Pet. App. 18a-19a).

The court also set aside the prohibition of dermal and eye contact with liquids containing benzene. The court held that the Secretary's finding that dermal contact poses risk of cancer would "pass muster" when viewed under the traditional substantial-evidence test (Pet. App. 25a). The court held, nonetheless, that the Secretary was obliged to "acquire" the radioactive benzene test recommended by Dr. Maibach before promulgating any standard based on skin absorption (*id.* at 26a-27a). No such experiment had been conducted before the Secretary promulgated his standard, but Dr. Maibach's testimony led the court to believe that definitive results could be made "readily available." The court held that the Secretary had therefore violated Section 655(b)(5)'s requirement to set standards based on "research, demonstrations, experiments, and such other information as may be appropriate," and on the "latest available scientific data in the field."

Because all of the standard's other requirements were "tied to" the permissible exposure limit and the dermal contact prohibition, the court set aside the entire standard (Pet. App. 33a).

SUMMARY OF ARGUMENT

I

The court of appeals has required the Secretary of Labor to show that the costs of regulating toxic substances under the Occupational Safety and Health Act are commensurate with the benefits of the regu-

lation. Although cost-benefit analysis may be a useful tool in ordinary cases of regulation, OSHA is no ordinary statute, and 29 U.S.C. 655(b)(5), the toxic substances provision, is no ordinary command. Section 655(b)(5) instructs the Secretary to ensure that "no employee will suffer impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life." The Secretary "shall" set "the" standard necessary to achieve the level of exposure that "most adequately assures, to the extent feasible," that the no-material-impairment criterion is met. It recapitulates its purpose as "the attainment of the highest degree of health and safety protection for the employee * * *." The statute simply leaves no room for the conclusion that the Secretary must balance costs against benefits in setting an exposure level.

The court of appeals found its cost-benefit requirement in 29 U.S.C. 652(8), which defines a health and safety standard as a rule regulating practices and conditions of employment "reasonably necessary or appropriate to provide safe or healthful employment." But a cost-benefit standard can be placed in this definitional clause only by main force. The legislative history of the entire Act contains not one mention of a cost-benefit study requirement, and there is no hint that Section 652(8) was intended to modify the substantive requirements of 29 U.S.C.

655(b)(5). Under the statutory scheme, an occupational health and safety standard is "reasonably necessary or appropriate" if it carries out the goals identified in the substantive parts of the statute. The benzene standard does so, and it therefore meets the statutory requirements. Here, as elsewhere in the law, the phrase "reasonably necessary" is a description rather than a limit. See, *e.g.*, *United States* v. *An Article of Drug * * * Bacto-Unidisk*, 394 U.S. 784, 786 n.2, 791-792 (1969); *Mourning* v. *Family Publications Service, Inc.*, 411 U.S. 356, 369 (1973).

The toxic substances provision itself requires the Secretary to achieve the lowest possible risk within the range of feasibility. The language, which is quoted above, shows that a more particular cost-benefit balance is unnecessary. The legislative history shows that Congress meant what it said. The principal concern of the draftsmen of the Act was toxic substances. The statutory language was attacked repeatedly as unyielding; the supporters of the statute did not reject this analysis but embraced it as a description of their purpose. When a compromise finally was struck, Congress decided to restrict the scope of Section 655(b)(5) to toxic or hazardous substances —rather than, as originally proposed, all industrial hazards—but to leave the force of the section unchanged. The nature of the compromise is readily understood: proponents of regulation obtained a sweeping statute concerning toxic substances, while opponents confined the strongest section of the statute to this particular hazard.

The word "feasible," although introducing cost considerations into the Secretary's decisions, does not permit a cost-benefit test to be employed in setting toxic substances standards. No one suggested in the legislative debates that "feasible" has any meaning other than its usual one: "capable of being achieved." No Member of Congress suggested that a standard is not "feasible" if, although achievable, it is too costly in relation to its benefits. The absence of such a suggestion is telling. Any construction of the statute that introduces a cost-benefit balance through the "feasibility" provision would render meaningless the non-material-impairment criterion of Section 655(b)(5). There is simply no reason to conclude that Congress drafted an internally contradictory statute.

The Fifth Circuit's approach is at war with Section 655(b)(5) in yet another way. Section 655(b)(5) requires the Secretary, in issuing standards for toxic materials, to act on "the best available evidence." This provision was inserted because Congress was aware of the "frightening gap" between "our knowledge about [toxic] substances, and what we need to know" (Leg. Hist. 1044-1045). Congress therefore authorized the Secretary to act on the basis of the "best available evidence" because "it [was] not intended that the Secretary be paralyzed by debate surrounding diverse medical opinions." *Id.* at 848. The Fifth Circuit's cost-benefit rule creates precisely the type of paralysis that Congress intended to avoid. In the present case, the best available evidence for benzene is simply inadequate to perform the type of risk assessment and cost-benefit analysis

desired by the Fifth Circuit. In the Secretary's view, he will be unable to issue any benzene standard that satisfies the court's test. Congress could not have intended to establish a cost-benefit requirement that could not be met on the basis of the best available evidence.

II

The court of appeals also erred in vacating the protective clothing requirement. The court held that the Secretary should not have established this provision without first "acquiring" the results of a series of tests using radioactive benzene suggested by Dr. Howard Maibach. But the Secretary's decision to include this provision without first acquiring the radioactive-benzene studies did not violate the requirement of 29 U.S.C. 655(b)(5) that the standard be based on the "best available evidence" or the requirement that it be based on "research, demonstrations, experiments, and such other information as may be appropriate." The protective clothing requirement was based on "research, experiments, and demonstrations." It also was based on the best evidence "available." Dr. Maibach's study was then not "available." Nor is it available today, except for "preliminary results." The predictions by him and industry counsel that studies with conclusive results could be performed in only six to twelve weeks proved unfounded. By requiring the Secretary to postpone the standard until allegedly "readily" available studies are conducted, the court of appeals again has

introduced the type of paralysis that Congress sought to avoid.

ARGUMENT

I

THE OCCUPATIONAL SAFETY AND HEALTH ACT DOES NOT REQUIRE THE SECRETARY TO ESTABLISH THAT THE COSTS OF PARTICULAR REDUCTIONS IN EXPOSURE TO TOXIC SUBSTANCES ARE JUSTIFIED BY QUANTIFIABLE BENEFITS

The court of appeals held that the Occupational Safety and Health Act conditions the Secretary's ability to order reductions in exposure to toxic substances on his ability to show that the benefit to the workers' health bears some quantifiable relationship to the costs of the regulation. The court conceded that no such requirement can be found in 29 U.S.C. 655(b)(5), which authorizes and sets the criteria for toxic substances regulations. The court found its requirement, instead, in a definitional provision of the Act that speaks of standards "reasonably necessary or appropriate" for public health. 29 U.S.C. 652(8). In the court's view, a cost-benefit rule is reasonable public health policy, and thus to be read into the Act through the definitional section. The court of appeals thought that it makes simple good sense to require the agency to determine that the benefits of its regulations are worthwhile when measured against the costs.

But the court of appeals was not at liberty to insist that the Secretary of Labor follow its approach in dealing with toxic substances. Although many statutes permit or require the kind of cost-benefit assessment that the court of appeals thought to be desirable, other statutes do not. See, *e.g.*, *Union Electric Co.* v. *EPA*, 427 U.S. 246 (1976) (the Clean Air Act contains no requirement that state implementation plans for air pollution be economically or technologically feasible, much less cost-beneficial); Comment, *Implementing the Anticancer Clauses of the Food, Drug and Cosmetic Act*, 44 U. Chi. L. Rev. 817 (1977) (discussing several statutes that regulate use of carcinogens without regard to cost). When a statute requires regulation in the name of safety without regard to the balance between costs and benefits, or even feasibility, neither the Executive Branch nor a court may require such a balance to be struck. *TVA* v. *Hill*, 437 U.S. 153, 193-195 (1978).

The toxic-substances provision of the Act does not go quite that far. 29 U.S.C. 655(b)(5) states that the Secretary "shall" set "the" standard that "most adequately assures, to the extent feasible" that "no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life." The section then recapitulates its goal as "the attainment of the highest degree of health and safety protection for the employee * * *." A statute written in such terms is an unmistakable instruction from Congress

that employee health is to be achieved even at great cost.[35] The policy of Congress is that cost may be considered only to determine what is "feasible." In the pages that follow, we show that neither the definitional provision of 29 U.S.C. 652(8) nor the "feasibility" language of Section 655(b)(5) requires the Secretary to engage in the sort of cost-benefit balancing proposed by the court of appeals.

A. The Definitional Phrase "Reasonably Necessary Or Appropriate" Does Not Impose A Cost-Benefit Test

The Fifth Circuit concluded that 29 U.S.C. 652(8), which defines an "occupational safety and health standard" as a rule that requires conditions, means, methods or processes "reasonably necessary or appropriate to provide safe or healthful employment," imposes a cost-benefit requirement on toxic substances

[35] Every court of appeals (other than the Fifth Circuit in this case) that has considered the role of costs in standard setting has held (either explicitly or implicitly) that the Secretary need not undertake a cost-benefit study before establishing a toxic substances regulation. *American Iron and Steel Institute* v. *OSHA*, 577 F.2d 825 (3d Cir. 1978), petitions for cert. pending, Nos. 78-918 and 78-919 (coke oven emissions); *Society of the Plastics Industry, Inc.* v. *OSHA*, 509 F.2d 1301 (2d Cir.), cert. denied, 421 U.S. 992 (1975) (vinyl chloride); *Industrial Union Department, AFL-CIO* v. *Hodgson*, 499 F.2d 467 (D.C. Cir. 1974) (asbestos dust). Cf. *Turner Co.* v. *Secretary of Labor*, 561 F.2d 82, 86 (7th Cir. 1977) (ban on "life-threatening hazards" such as industrial carcinogens would not be subject to any cost-benefit test, even though regulation of other hazards under a section other than Section 655(b)(5) is so subject); *RMI Co.* v. *Secretary of Labor*, No. 78-3312 (6th Cir. Mar. 13, 1979), slip op. 10-12 (same).

standards issued under 29 U.S.C. 655(b)(5). The court of appeals is wrong. The phrase "reasonably necessary or appropriate" is not a limitation on the Secretary's powers or a substantive standard of any sort. It is, rather, a description of the rules produced by adherence to the criteria laid down elsewhere in the statute.[36]

Even if the phrase is given substantive meaning, however, it is not a brake on the exercise of powers

[36] Nothing in the lengthy legislative history of the Act suggests that the "reasonably necessary or appropriate" language is a description of the Secretary's duty, rather than (as we suggest) a description of rules that result if the Secretary conscientiously carries out the duties established by the substantive sections of the statute.

All but one of the original bills (see Leg. Hist. 659) contained a definition of "occupational safety and health standard" similar to the definition enacted as 29 U.S.C. 652(8). Some used only the phrase "reasonably necessary" rather than "reasonably necessary or appropriate," but otherwise they were identical. Leg. Hist. 3, 35, 78, 235, 532, 601, 631, 683, 725, 768, 937. Both the Senate and the House versions of the Act used the phrase "reasonably necessary or appropriate." *Id.* at 235, 937. No suggestion was made anywhere in the committee reports that the definition was intended to limit the scope of permissible standards. See *id.* at 166, 866. No such claim was made in the floor debates. The absence of any such assertion is telling, inasmuch as critics of the Act in both chambers assailed the Act for its requirement in Section 655(b)(5) that "absolute" health protection be provided to employees regardless of cost (see pages 59, 4a, 6a, *infra*). Indeed, so far as we can find, no mention was ever made of the phrase, aside from repeating it in the section-by-section explanations in the committee reports. In short, from beginning to end, the legislative record is devoid of evidence that the definition was meant to modify or even to describe the Secretary's duties under 29 U.S.C. 655(b)(5).

granted by other sections of the same Act. Where "the empowering provision of a statute states simply that the agency may 'make . . . such rules and regulations as may be necessary to carry out the provisions of [an] Act,' * * * the validity of a regulation promulgated thereunder will be sustained so long as it is 'reasonably related to the purposes of the enabling legislation.'" *Mourning* v. *Family Publications Service, Inc.*, 411 U.S. 356, 369 (1973) (footnote omitted). For example, where a statute authorized the FDA to promulgate drug regulations "necessary" to achieve the goal of a public health statute, this Court, in sustaining the regulations, observed that "[i]t is enough for us that the expert agency charged with the enforcement of remedial legislation has determined that such regulation is desirable for the public health * * *." *United States* v. *An Article of Drug* * * * *Bacto-Unidisk*, 394 U.S. 784, 786 n.2, 791-792 (1969). Statutes that authorize regulations "necessary or appropriate" to carry out the provisions of the statute have been similarly construed.[37] *FPC* v. *Texaco Inc.*,

[37] Where a federal statute authorizes an agency to issue regulations to further the goals of a statute, this Court regularly has held that the courts may not set aside the agency's regulations unless they are inconsistent with the goal of the statute or violate a requirement of the statute. *Bowles* v. *Willingham*, 321 U.S. 503, 519 (1944); *SEC* v. *Chenery Corp.*, 332 U.S. 194, 207 (1947); *American Trucking Associations* v. *United States*, 344 U.S. 298 (1953); *United States* v. *Storer Broadcasting Co.*, 351 U.S. 192, 201-203 (1956); *Thorpe* v. *Housing Authority of the City of Durham*, 393 U.S. 268, 280-281 (1969); *FCC* v. *National Citizens Committee for Broadcasting*, 436 U.S. 775, 796-797 (1978); *FERC* v. *Pennzoil Producing Co.*, No. 77-648 (Jan. 16, 1979), slip op. 8.

The Act provides that "[t]he determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole." 29 U.S.C. 655(f). The courts of appeals agreed that this substantial evidence test requires that factual determinations made by the Secretary be supported by substantial evidence. Policy determinations made by the Secretary need only be consistent with the statutory goal and any statutory requirements. See *Associated Industries of New York State, Inc.* v. *United States Department of Labor*, 487 F.2d 342, 347-350 (2d Cir. 1973); *Florida Peach Growers Ass'n* v. *United States Department of Labor*, 489 F.2d 120, 127-129 (5th Cir. 1974); *Industrial Union Department, AFL-CIO* v. *Hodgson*, *supra*, 499 F.2d at 472-476; *Synthetic Organic Chemical Manufacturers Association* v. *Brennan*, 503 F.2d 1155, 1158-1160 (3d Cir. 1974); *Society of the Plastics Industry, Inc.* v. *OSHA*, *supra*, 509 F.2d at 1303-1304; *American Iron and Steel Institute* v. *OSHA*, *supra*. The Fifth Circuit accepted this construction of Section 655(f) (Pet. App. 4a-5a). We believe that this conclusion, about which the parties are not in dispute, is correct. It shows that the usual principles of review of regulations, discussed in the preceding paragraph and in the text, must be applied here.

417 U.S. 380, 394 (1974); *Permian Basin Area Rate Cases*, 390 U.S. 747, 776 n.40 (1968); *United States* v. *Bush & Co.*, 310 U.S. 371, 380 (1940). And, where a statute permitted the ICC to establish "reasonable" regulations concerning railroad car availability and service, this Court concluded that the ICC could "rationally" conclude that its regulations served the statutory purpose despite the contention of the railroads that the short-term injury of the regulations far outweighed the long-term benefits. *United States* v. *Allegheny-Ludlum Steel Corp.*, 406 U.S. 742, 752-753 (1972).

The phrase "reasonably necessary or appropriate to provide safe or healthful employment" is in this tradition. So long as the standard meets the other requirements of the Act, Section 652(8) permits the Secretary to issue any standard that he rationally concludes is appropriate for the protection of the health and safety of employees under the substantive provisions of the Act.

The Fifth Circuit's reliance on *Aqua Slide 'N' Dive Corp.* v. *CPSC*, 569 F.2d 831 (5th Cir. 1978), which construes part of the Consumer Product Safety Act, was unwarranted. Although both statutes refer to standards "reasonably necessary" to achieve certain goals, the structures of the statutes are otherwise quite dissimilar. The "reasonably necessary" phrase in the Consumer Product Safety Act, 15 U.S.C. 2058 (c)(2)(A), appears in a clause authorizing the Consumer Product Safety Commission to set consumer product safety standards that are "reasonably necessary to eliminate or reduce *an unreasonable risk* of injury * * *" (emphasis added). The phrase thus appears in the clause granting the power to regulate, rather than in a collateral definition. The Consumer Product Safety Commission's responsibility, moreover, is to find that its rules are "reasonably necessary to eliminate or reduce an unreasonable risk of injury"; the Commission must consider "the probable effect of such rule upon the utility, cost, or availability of [the affected] products" and "any means of achieving the objective of the order while minimizing adverse effects on competition or disruption or dislocation of manufacturing and other commercial practices." 15 U.S.C. 2058(c)(1)(C), (D) and (2). Before the Commission may ban a product altogether as unsafe it must find that "no feasible consumer product safety standard * * * would adequately protect the public from the unreasonable risk of injury associated with such products." 15 U.S.C. 2058(c)(2)(C). The Consumer Product Safety Act thus recognizes that some products (*e.g.*, knives) pose a risk of harm that should be tolerated in light of their benefits; the Act permits regulation only of risks that are "unreasonable."[38] In contrast, OSHA does not limit the Secretary to regulating only "unreasonable" health risks; it authorizes the Secretary to eliminate, if feasible, all risks of material impairment that toxic substances pose to employees' health.

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[38] The Fifth Circuit observed in *Aqua Slide* that the CPSC cannot determine whether an "unreasonable risk" is presented without balancing the severity of the injury that may result from the product, discounted by the unlikelihood of the injury, against the harm the regulation itself will impose on manufacturers and consumers. 569 F.2d at 839.

Consumer product safety risks may be reasonable because the very feature that presents a risk (*e.g.*, the sharp edge of a knife) also offers a benefit. Consumers ought to be able to choose whether the risk to them is worth the benefit to them, and it is understandable that only hazards which are "unreasonable" are regulated. In contrast, occupational health hazards pose risks only to employees. The benefits (lower production costs) accrue in the main to employers and consumers. It is therefore understandable that 29 U.S.C. 655(b)(5) authorizes the Secretary to regulate all risks of material impairment to health caused by toxic substances rather than merely "unreasonable" health risks.

B. Section 655(b)(5) Prohibits Basing A Standard On A Cost-Benefit Test

If the Court agrees with the argument that 29 U.S.C. 652(8) does not require the application of cost-benefit criteria in making decisions about the level of exposure to toxic substances, it then must decide whether 29 U.S.C. 655(b)(5) requires cost-benefit analysis. We have pointed out above (see pages 41-42, *supra*) that the language of the statute contains no hint of such a requirement. To the contrary, the Secretary "shall" select "the" standard that "most adequately assures, to the extent feasible" that "no" employee shall suffer, even if exposed to the toxic substance "for the period of his working life." The Secretary has followed this mandate by ascertaining the level of exposure to a substance at which employees will not risk incurring the disease and then determining whether this exposure level is "feasible." If it is not feasible to attain the safe level, the Secretary adjusts the standard accordingly. But a court may not override this process with a cost-benefit balancing that could well require the Secretary to tolerate additional occupational illness in order to achieve lower costs when a stricter standard would be feasible; that squarely violates the no-material-impairment rule of the statute.

But no statute is so plain that resort to the legislative history is forbidden. See, *e.g.*, *United States* v. *Culbert*, 435 U.S. 371, 374 n.4 (1978); *Train* v. *Colorado Public Interest Research Group, Inc.*, 426 U.S. 1, 10 (1976). We therefore examine the legislative history of the Act and show that nothing in

the history supports the court of appeals' creation of a cost-benefit test. We then turn to a number of logical problems in the interpretation of the "feasibility" language of Section 655(b)(5) on which respondents rely.

1. *The legislative history establishes that Congress wanted the Secretary to regulate toxic substances by considering costs only as part of "feasibility"*

Foremost among the concerns of Congress in enacting OSHA was the ever-increasing number of toxic materials and harmful physical agents in the workplace. Leg. Hist. 142-143, 159-160, 411-415, 503, 510, 845-846, 1061. The Senate Committee on Labor and Public Welfare, for example, reported that toxic agents were a pernicious threat to employee health:

> Workers in the dusty trades still contract various respiratory diseases. * * * Carcinogenic chemicals, lasers, ultasonic [*sic*] energy, beryllium metal, epoxy resins, pesticides, among others, all present incipient threats to the health of workers. * * * It is estimated that every 20 minutes a new and potentially toxic chemical is introduced into industry. New processes and new sources of energy present occupational health problems of unprecedented complexity.
>
> Recent scientific knowledge points to hitherto unsuspected cause-and-effect relationships between occupational exposures and many of the then so-called chronic diseases—cancer, respiratory ailments, allergies, heart disease, and others. In some instances, the relationship appears to be direct: asbestos, ionizing radiation, chromates, and certain dye intermediaries, among others, are directly involved in the genesis of cancer. In other cases, occupation exposures are implicated

> as contributory factors. The distinction between occupational and nonoccupational illnesses is growing increasingly difficult to define.

Id. at 142.[39]

Death from such "silent killers" [40] was occurring because many employers had little economic incentive to provide healthful workplaces. "[M]any employers —particularly smaller ones—simply cannot make the necessary investment in health and safety, and survive competitively, unless all are compelled to do so." *Id.* at 144 (Senate Report). Because employees often moved from job to job, "an employer investing in current occupational health precautions would receive no future benefits, not even in the reduction of workmen's compensation costs. He might be paying for the past neglect of another employer." *Id.* at 854 (House Report).

In these circumstances, Congress concluded, the best approach was to impose a duty on all employers to provide workplaces as free from health hazards as possible. Congress recognized that achievement of this goal would require substantial investment in health protection (Leg. Hist. 444, 510, 525-526, 1004, 1030, 1040, 1150-1151), and that these costs "would be put into consumer goods * * *." *Id.* at 444 (Sen. Yarborough).[41] But Congress concluded that the ex-

[39] The House Committee on Education and Labor likewise identified exposure to toxic substances as a principal concern. *Id.* at 844-846.

[40] Leg. Hist. 1044-1045 (Rep. Udall).

[41] Congress anticipated that to some extent the cost of compliance would be recovered in savings in health care, workmen's compensation, lost wages and lost productivity. *Id.* at 142, 844-845, 1061.

pense of providing a safe and healthful place to work is a necessary and reasonable cost of doing business. Senator Eagleton observed that "[t]he costs that will be incurred by employers in meeting the standards of health and safety to be established under this bill are, in my view, reasonable and necessary costs of doing business. Whether we, as individuals, are motivated by simple humanity or by simple economics, we can no longer permit profits to be dependent upon an unsafe or unhealthy worksite." *Id.* at 1150-1151. Senator Williams, perhaps the principal author of the Act, stated that the cost of compliance was "the price we should pay for the 80 million workers in America." *Id.* at 444.[42]

Congress recognized that health standards would significantly increase the cost of doing business. It required these costs to be borne so long as it was feasible to do so. This fixes the balance between costs

[42] Senator Yarborough, a co-sponsor of the bill that was ultimately enacted, replied to the claim that the bill would be expensive (*id.* at 510):

> One may well ask too expensive for whom? * * * Is it too expensive for the employee who loses his hand or leg or eyesight? Is it too expensive for the widow trying to raise her children on meager allowance under the workmen's compensation and social security? * * *
>
> * * * * *
>
> We are talking about people's lives, not the indifference of some cost accountants. We are talking about assuring the men and women who work in our plants and factories that they will go home after a day's work with their bodies intact.

and benefits in a way that favors health. Consequently, Congress decided, economic hardship may not be a ground for obtaining a variance from a standard. 29 U.S.C. 655(b)(6)(C), 655(d); Leg. Hist. 160. For toxic substances, it decided that "the" standard which "most adequately assures, to the extent feasible" that "no" employee would suffer material health impairment during his entire working life must be adopted. But no Member of Congress so much as suggested that, because of cost-benefit considerations, the Secretary must tolerate risks, caused by toxic substances, that could be eliminated feasibly. Indeed, we can find no reference in the legislative history to cost-benefit techniques in any context whatsoever. The silence carries a persuasive message.[43]

The pattern and structure of the Act also demonstrate Congress' preference for health protection without regard to a particular balance against costs. Congress declared its purpose to be "to assure so far as possible" that every worker in the nation has a safe and healthful working environment. 29 U.S.C. 651(b). The Act imposes on all employers a duty to "furnish to each of his employees employment and a place of employment which are free from recognizable hazards that are causing or are likely to cause death or serious physical harm to his employees." 29 U.S.C. 654(a)(1). In adopting national consensus standards and established federal standards during the first two

[43] The Appendix to this brief contains a further discussion of the genesis of the toxic substances provision.

years of the Act, the Secretary was required to choose the standards that would result in improved safety or health. In the event of a conflict among possible standards, the Secretary was required to "promulgate the standard which assures the greatest protection of the safety or health of the affected employees." 29 U.S.C. 655(a). If the Secretary adopts a permanent standard that differs from an existing national consensus or established federal standard, the Secretary must explain why the change will better effectuate the purposes of the Act. 29 U.S.C. 655(b)(1). Where the standard deals with toxic substances, 29 U.S.C. 655(b)(5) requires that the Secretary adopt "the" standard which "most adequately assures, to the extent feasible, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life." Variances from standards may be obtained, but only on carefully limited grounds—financial hardship is *not* a ground for a variance.[44] 29 U.S.C. 655(b)(6)(C) and 655(d).

[44] Although financial hardship is not an excuse for noncompliance, the Secretary's enforcement program takes hardship into account in working out abatement programs consistent with the purposes of the Act. The Secretary's Industrial Hygiene Field Operations Manual, which sets forth procedures for enforcement of health standards, states:

> The employer's economic cost of abatement will not be considered to be a factor in the issuance of a citation. However, if the cost of utilization of effective engineering or administrative controls, or combination, which would bring the employer into compliance with permissible

See note 7, *supra*. Financial hardship is to be relieved directly only through small business loans to assist employers in complying with standards. 15 U.S.C. 636.

In short, at every turn in the statute Congress expressed a preference for maximum feasible health protection.[45] That Congress failed to qualify this goal in any way with a requirement that the benefits be measurable, refused to allow variances on the ground of financial hardship, and limited its only financial relief to small business loans demonstrates that Congress carefully did not require any cost-benefit test. The court of appeals erred in reading into the statute "what Congress has studiously omitted." *FTC* v. *Simplicity Pattern Co.*, 360 U.S. 55, 67 (1959);

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exposure limits would so seriously jeopardize his financial condition as to result in the probable shutdown of his establishment or a substantial part, then only a personal protective equipment program should be required in the interim, and an extended abatement date should be granted to permit the extended implementation of feasible engineering or administrative controls taking into account the employer's financial condition. The burden of proof of economic infeasibility rests upon the employer. Any abatement date based on economic grounds shall be approved by the Regional Administrator.

Empl. Safety & Health Guide (CCH) ¶ 4483.80, § 3.8(b)(1) (1979). See also *Atlantic & Gulf Stevedores, Inc.* v. *OSHRC*, 534 F.2d 541 (3d Cir. 1976).

[45] See *SEC* v. *Sloan*, 436 U.S. 103, 121 (1978); *Train* v. *Natural Resources Defense Council, Inc.*, 421 U.S. 60, 86 (1975) (scope of agency's rulemaking powers determined in part by examination of the pattern and structure of the statute in question).

Great Atlantic & Pacific Tea Co. v. *FTC*, No. 77-654 (Feb. 22, 1979), slip op. 8-9.

2. *The requirement that standards be "feasible" refers to practicability rather than to a cost-benefit balance*

29 U.S.C. 655(b)(5), which authorizes toxic substance standards, has both a procedural directive and a substantive criterion.[46] Procedurally, the Secretary must consider the best available evidence, the latest experience in the field; he must base standards on experiments, research, and such other information as may be appropriate. Substantively, the Secretary must set "the" standard that "most adequately assures, to the extent feasible" the "highest degree of health and safety protection." There is no room in this scheme for the Secretary to set standards by weighing the value of life and ~~death~~ health against the cost of their preservation. Congress has done that; it struck the balance in favor of maximum health protection, subject only to the requirement of feasibility. The "lowest feasible level" policy of the Secretary (see pages 20-25, *supra*) satisfies the imperative. The Fifth Circuit's cost-benefit test violates it.[47]

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[46] The language is quoted in full at page 3, *supra*.

[47] This does not mean that the Secretary may never weigh costs and benefits where sufficient data exist to do so. To the contrary, the Secretary is required to set priorities in the use of his own time and resources according to the severity of the need for achieving better health and safety protection against various hazards. 29 U.S.C. 655(g). In determining where the need for prompt rulemaking is the greatest, the Secretary may take the relative costs and benefits of the

Respondents may contend that the phrase "to the extent feasible" in Section 655(b)(5) itself imposes a cost-benefit requirement. The court of appeals did not accept this argument, and for good reasons.

The word "feasible" does not require any cost-benefit test. The ordinary meaning of "feasible" is "capable of being done." See *Webster's Third New International Dictionary* 831 (1971).[48] The word does not refer to the desirability or benefit of doing something; it refers, instead, to the ability of doing something. That is how Congress has consistently employed "feasible" in health or safety legislation. Congress' understanding is clearly conveyed by another statute enacted the same week as OSHA.[49] This

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existing standards and the proposed standards into account. But once the Secretary decides to issue a standard for toxic substances, he must satisfy the requirements of Section 655(b)(5).

[48] See also I *Compact Oxford English Dictionary* 973: "Capable of being done, accomplished or carried out; possible, practicable."

[49] Section 211(c)(2)(A) and (B) of the Clean Air Act authorizes the EPA to regulate, control or prohibit automobile fuel additives. Control or prohibition of additives that endanger the public health was permitted only after "consideration of other technologically or economically *feasible* means of achieving emission standards * * *." In contrast, control or prohibition of additives which may impair effective operation of emission control devices was permitted only after consideration of "*a cost benefit analysis*" comparing device performance with and without the control or prohibition. 42 U.S.C. 7545(c)(2)(A) and (B) (emphasis added).

Later Congresses likewise recognized the difference between a feasibility requirement and a requirement that economic effects be balanced or considered. The Consumer Product Safety Act of 1972 permits the Consumer Product Safety Commission to regulate product hazards after it considers the risks presented by a product and the economic effects of its proposed safety rule. 15 U.S.C. 2058 (c)(1)(C) and (D). The Commission may take the more drastic step of banning the product altogether only after finding that no "feasible" safety rule would provide sufficient protection. 15 U.S.C. 2057. Section 325 of the Energy Policy and Conservation Act of 1975, 42 U.S.C. 6295, requires promulgation of energy conservation standards. Section 325(a) specifies that a standard must be "economically justified." A standard is economically justifiable only if the Secretary of Commerce finds both that the benefits of the standard outweigh its costs and that the standard is "economically feasible." "Feasibility" is defined as "capable of being carried out." S. Rep. No. 94-516, 94th Cong., 1st Sess. 172 (1975); H.R. Conf. Rep. No. 94-700, 94th Cong., 1st Sess. 172 (1975).

Court, too, has understood that "feasible" means capable of achievement. See *Union Electric Co.* v. *EPA*, *supra*. Respondents do not dispute that the benzene standard is feasible in this sense—it can be achieved at bearable cost with available technology.[50]

Moreover, if "to the extent feasible" means "to the extent justified by the costs of doing so," then most of Section 655(b)(5) is sapped of meaning. The words requiring the Secretary to set "the" standard

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[50] Economic considerations necessarily play a substantial role in the Secretary's determination that a particular level of exposure is feasible. It may be technologically possible to make benzene on the moon, but if doing so were the only way to reduce exposure, the suggestion would not be feasible. The Secretary takes economic considerations into account in determining what is feasible. For example, considerations of economic feasibility were important in setting the level of exposure to cotton dust in certain textile operations (43 Fed. Reg. 27360 (1978)), and the Secretary allowed the inorganic lead industry additional time (as much as 10 years) to imple-

that "most" adequately assures that "no employee will suffer material impairment of health * * * even if [exposed to the hazard] for the period of his working life" would become nugatory. A construction that renders state language meaningless should be avoided if possible. *Weinberger* v. *Hynson, Westcott & Dunning*, 412 U.S. 609, 633 (1973); *Jarecki* v. *G.D. Searle & Co.*, 367 U.S. 303, 307 (1961). Here there is no reason why these words should be disregarded—they are the heart of the statute. Indeed, giving the "feasibility" language a cost-benefit meaning would turn the statute on its head. Standards for hazards other than toxic substances and harmful physical agents are governed by other sections that lack the "feasibility" phrase. If the feasibility language is the source of a cost-benefit requirement, then *only* toxic substances rules need to meet such a test. That is topsy-turvy, because the entire structure of the Act establishes that Congress wanted toxic substances placed under controls far more strict than those applicable to simple hazards (such as slippery floors, which also are subject to regulation). See pages 6a-7a in the Appendix, *infra*.

The submission that "feasible" means "capable of being achieved" within the range of acceptable costs

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ment the exposure levels for similar reasons (43 Fed. Reg. 52978, 53008 (1978)). In this case the Secretary examined the capitalization of firms, the profitability of businesses, and other factors in determining that the cost of the standard was bearable. See Pet. App. 134a-163a. Because respondents do not dispute the economic feasibility of the benzene standard, it is unnecessary to discuss here what criteria the Secretary should use in making these judgments.

(see note 50, *supra*) is supported by the legislative history of Section 655(b)(5). Section 655(b)(5) was inserted to assure "so far as possible" that standards would prevent material health impairment:

> Such standards should be directed at assuring, so far as *possible*, that no employee will suffer impaired health or functional capacity, or diminished life expectancy, by reason of exposure to the hazard involved, even though such exposure [to the hazard] may be over the period of his entire working life.

Leg. Hist. 147 (Senate Report) (emphasis added).

In the Senate members objected to the original language of Section 655(b)(5), which would have required the Secretary to establish the standard that "most adequately and feasibly assures" that no employee will suffer material health impairment. It was argued that this language would mandate "absolute safety," which is an "impossibility." Leg. Hist. 480-481. Other criticism, in the same vein, is discussed in the Appendix, *infra*, 4a-8a. In response to this criticism, Congress restricted Section 655(b)(5) to standards for "toxic materials or harmful physical agents," rather than all standards, as was originally proposed, and modified the feasibility language to its present version. Leg. Hist. 502-503. It is difficult to believe that this debate would have occurred without mention that the word feasible was intended to impose a cost-benefit requirement, if that were Congress' purpose. Not once, however, throughout the entire legislative history of 29 U.S.C. 655(b)(5) is there any suggestion of such a meaning. In sum, the plain language of Section 655(b)(5) and its legisla-

tive history are irreconcilable with the Fifth Circuit's cost-benefit test.

3. *The requirement that the Secretary make decisions on the basis of the "best available evidence" precludes any role for cost-benefit analysis if the necessary data are not "available"*

Section 655(b)(5) instructs the Secretary to act on the basis of the "best available evidence." Congress was aware of the "frightening gap" between "our knowledge about [toxic] substances, and what we need to know" (Leg. Hist. 1044-1045). The best-available-evidence provision was inserted because "it [was] not intended that the Secretary be paralyzed by debate surrounding diverse medical opinions." *Id.* at 848. This provision fortifies the conclusion that a cost-benefit analysis is unnecessary under the statute; even if such an analysis sometimes can be conducted, the data are not always "available." Where, as here, "the factual finger points [but] does not conclude" (*Society of the Plastics Industry, Inc.* v. *OSHA*, 509 F.2d 1301, 1308 (2d Cir.), cert. denied, 421 U.S. 992 (1975)), the Secretary can promulgate standards now whether or not more complete evidence could be made available in the future.

The significance of the best-available-evidence provision is two-fold. First, it supports our construction that the Act never requires the Secretary to engage in cost-benefit balancing. Because Congress was aware of the gaps in medical research concerning toxic substances,[51] Congress could not have intended

[51] As of 1969 more than 6,000 chemicals were in use in occupational settings, and it was estimated that every twenty minutes a new and potentially toxic substance was introduced into industry. Health authorities could demonstrate safe levels of exposure for only 500 of these substances. Leg. Hist. 412, 1044. Emphasizing the "frightening gap between our knowledge about [toxic] substances, and what we need to know," Rep. Udall stated that it was not possible to calculate "how many workers have been struck down by silent killers in the form of corrosive chemicals, noxious fumes, and debilitating dust particles that have become commonplace ingredients of the manufacturing process." Leg. Hist. 1044-1045.

to impose a cost-benefit requirement that in numerous instances would frustrate all regulation because even the best available evidence would not be good enough. To construe the statute to require quantification not possible even with the "best available evidence" would "impute to Congress a purpose to paralyze with one hand what it sought to promote with the other." *Weinberger* v. *Hynson, Westcott & Dunning, supra*, 412 U.S. at 631, quoting *Clark* v. *Uebersee Finanz-Korp.*, 332 U.S. 480, 489 (1947). Second, even if the Act imposes a cost-benefit requirement where evidence *is* available to assess costs and benefits, that requirement must yield where the best available evidence is insufficient. Either construction of the best-available-evidence clause requires reversal in this case, because the court of appeals conceded that the best available evidence is not good enough to enable the Secretary to determine the relationship between exposure to benzene and risk of cancer (Pet. App. 19a n.23).

This is enough, we submit, to show that the Fifth Circuit's approach should be rejected. But because the court of appeals apparently thought that its cost-benefit test would not be excessively burdensome, we

try to show in the next few pages that the court is wrong. Its two-step test imposes the very paralysis that Congress sought to avert.

Under the court of appeals' approach the Secretary must quantify the cancer risk, that is, construct a dose-response curve showing how much cancer is caused by each of the low levels of exposure in question (1 to 10 ppm). Once the cancer risk is measured, with whatever degree of accuracy the court requires, the Secretary must demonstrate that the health benefits bear a "reasonable relationship" to the cost of achieving them. Although serious methodological obstacles attend the second step,[52] the Secretary will be unable to satisfy even the first step in many cases.

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[52] Even when available data are sufficiently reliable to permit the probable health benefits of a standard to be predicted, accurately, there are problems in using cost-benefit criteria to set an exposure standard where, as here, it is possible to set a "feasible" exposure limit and reduce the risk of employees more directly. The most important difficulty in setting a higher-than-feasible exposure level using cost-benefit techniques is placing an economic value (implicit or explicit) on life, health, bereavement, pain and suffering, and other consequences of occupational disease and death. There is no generally accepted method for valuing such considerations, even implicitly. See Senate Comm. on Governmental Affairs, 95th Cong., 2d Sess., Study on Federal Regulation, Vol. VI, at XXIV (Comm. Print 1978). For a discussion of the various methods occasionally proposed to quantify the value of life and other intangibles, see 41 Fed. Reg. 46742, 46751 (1976) (coke-oven-emissions preamble). See generally Fried, *The Value of Life*, 82 Harv. L. Rev. 1415 (1969); Rhoads and Singer, *What is Life Worth?*, 51 Pub. Interest 74 (Spring 1978). Second, there is no general agreement concerning whether a stream of health benefits and saved lives extending into the future should be discounted to present value in the same way that

The court of appeals' approach seems to require the Secretary simply to identify the benefits of reducing exposure from 10 ppm to 1 ppm, an entire order of magnitude. Relatively accurate measurements of such benefits eventually may be within the reach of medical science, as the court of appeals thought. But the court of appeals' analysis cannot logically be confined to changes in this magnitude. It is entirely fortuitous that the national consensus standard of benzene exposure was 10 ppm; the court of appeals' approach would require the Secretary to identify the benefits of moving from 5 ppm to 1 ppm, if that had been the proposed change. Or if the Secretary had proposed a decrease from 10 ppm to 5 ppm, the court of appeals would have demanded to know the benefits of that course. The smaller the proposed decrease in question, the more difficult it is to learn its benefits, and thus the more difficult it becomes to satisfy the court of appeals' requirements.

In fact, despite the superficial reasonableness of the court's approach, its test could not be satisfied until the Secretary has learned and can quantify with

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future economic values are generally discounted in awarding tort damages. Third, the Secretary has found that industry tends to overestimate the cost of implementing proposed standards, which makes it difficult accurately to weigh benefits against costs. For example, industry asserted that the Secretary's vinyl chloride standard would seriously disrupt the industry. In fact, however, the industry promptly complied, at a cost much lower than it had projected, by devising new technology to meet the standard. Vinyl chloride production has continued to increase. See Doniger, *Federal Regulation of Vinyl Chloride: A Short Course in the Law and Policy of Toxic Substances Control*, 7 Ecol. L.Q. 497 (1978).

useful precision the benefits to be obtained by reducing exposure through each part of the critical range. Unless the Secretary can learn these savings, he will be confronted with the demand in tomorrow's case that he show what *part* of a reduction in exposure contributes to what *part* of the saving of life. For example, if 10 years from now the Secretary learns with satisfactory certainty that a reduction in exposure to benzene from 10 ppm to 1 ppm would save 100 lives every year, industry will respond: "How do you know that a reduction to 1 ppm is necessary? What if all of the savings are achieved by a drop to 5 ppm, making the further reduction superfluous?" And that response will have substantial force if, as is often the case, the first step of a reduction (say, from 10 ppm to 5 ppm) can be achieved quite easily, while the further five-fold reduction to 1 ppm is costly. If 95% of the cost of reducing exposure from 10 ppm to 1 ppm lies in the reduction from 5 ppm to 1 ppm, then—if the court of appeals is correct—the Secretary surely must show what benefits are achieved by the reduction from 5 ppm to 1 ppm. It will not be enough to show the benefits of the entire drop; they must be shown segment-by-segment.[53]

[53] In other words, the court's approach would call for substantial evidence that risk drops as, say, a linear function of exposure rather than as a quadratic function. If the dose-response curve looks more like a parabola than like a straight line, the gains from reducing exposure below a certain level may become vanishingly small. But because of difficulties in the data (discussed in the text *infra*), the method by which results are extrapolated from high levels to low ones must be based on a non-verifiable choice of shape for the curve. The

It should be clear, however, that medical science cannot supply sufficiently useful approximations in such an exercise. The very obstacles that prevented the ~~Secretary~~ Secretary from attempting to measure the benefits of a reduction from 10 ppm to 1 ppm demonstrate this. Given the deficiencies in studies of the consequences of human exposure to benzene, it will be years before science accumulates enough information on even so substantial a decrease. This is so principally because there is very little information available on the actual concentrations of benzene at which health effects have been observed. Unless concentrations can be identified with some accuracy, scientists cannot extrapolate from their observations. Moreover, because leukemia often does not become manifest until long after the exposure to its cause (see Pet. App. 117a), it will be decades before all of the cancers caused by the exposure at the 10 ppm level are discovered (see Exh. 2-58 at 50-56). The exposure records of many workers exposed to benzene at other levels in other years may be lost—if any were kept—and this hinders reconstruction of a group of exposed workers for pur-

decision whether to try to fit a linear rather than a parabolic curve to the known observations, given the lack of adequate knowledge about how cancer is caused, is a choice of policy rather than of fact. In these circumstances the choice of one approach over another could not be justified by substantial evidence. Extrapolations based on a model so chosen thus could not answer the court of appeals' apparent demand for "harder" data. See McGarity, *Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA*, 67 Geo. L.J. 729, 735 n.27, 806 (1979).

poses of comparison.[54] Finally, because workers move from job to job, and may be exposed to different carcinogens in different jobs, it is quite difficult to determine which of the observed cancers in any group are attributable to exposure (or to how much exposure) to benzene.

These formidable difficulties pertain to the measurement of the incidence of cancer at the 10 ppm level. The difficulties in estimating the amount of cancer at the 1 ppm level—or any other level that is not now employed—are even more serious. If analysis of the data concerning cancers occurring at high levels of exposure leads to uncertainties, extrapolations to lower levels from these data are even more uncertain (Pet. App. 119a-120a).

The court of appeals did not give any reason for concluding that these difficulties and uncertainties can be overcome. The Secretary, who has a substantial scientific staff and a decade's experience in the

[54] For example, the Infante study of Goodyear employees exposed between 1940 and 1949 (see note 17, *supra*) was frustrated by the unavailability of sufficiently accurate data about exposure levels (Exh. 2-5 at 3; Tr. 806, 813-814, 1055-1056, 1156, 2506-2507). The data showed exposure peaks in some cases exceeding 200 ppm, but they did not reveal how much of the total exposure was attributable to these peaks and how much to the approved levels (19 ppm to 100 ppm). It cannot be determined whether the workers wore respirators in some situations, thus reducing exposure. Dr. Infante concluded that no reliable estimates of exposure could be established, and thus that it was not possible to establish a correspondence between the level of exposure and risk (see note 56, *infra*). The other studies in the record suffer from the same deficiencies (Pet. App. 99a-104a, 120a-122a, 160a).

administration of toxic substances regulation, has concluded that they cannot, at least within the foreseeable future. The Secretary's view that there is much to be learned, and much progress to be made, before risk assessments could be devised to meet the court of appeals' demands is consistent with the Interagency Regulatory Liaison Group's *Report on Scientific Bases for Identifying Potential Carcinogens and Estimating Their Risks* (Feb. 6, 1979). This *Report*, prepared by representatives of OSHA, the Consumer Product Safety Commission, the Food and Drug Administration and the Environmental Protection Agency, concluded that the state of the art permits only a "rough estimate * * * which may be useful in setting priorities among carcinogens and in obtaining a very rough idea of the magnitude of the public health problem posed by a given carcinogen." *Id.* at 76, 77. And even that much—which does not include determination of measurable benefits of the sort envisioned by the Fifth Circuit—can be achieved only if the data are available.[55]

[55] We do not mean by this that analyses of the costs of achieving a given level of protection are useless or should be avoided. Far from it; they provide information that is in some cases very valuable. The President has encouraged their use. Exec. Order No. 12044, 43 Fed. Reg. 12661, 12663 (1978). In recognition of their value, the President has proposed legislation that would, if adopted, require any agency in promulgating a major rule to prepare "an analysis of the projected benefits and the adverse economic and other effects of the rule" and either an explanation "why the rule attains its objectives, in a manner consistent with applicable statutes, with less adverse economic effects than the other alternatives con-

The Secretary, under a statutory obligation to use the best "available" evidence, resolved the uncertainties presented here in favor of safety. We have discussed in detail at pages 15-25, *supra*, how the Secretary weighed the competing considerations and how he resolved the numerous uncertainties. The court of appeals did not fault the Secretary's performance in this respect. Because the Secretary did the best he could with the best "available" evidence, the court of appeals' insistence that the Secretary create more

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sidered" or "why an approach entailing greater adverse economic effects was selected." S. 755, 96th Cong., 1st Sess. § 3 (1979). Our point here, rather, is that the cost analysis of this sort is quite different from a cost-benefit balancing for setting the level of protection in the first instance.

The Secretary also uses risk-assessment techniques where that is possible to evaluate whether a reduction in exposure would produce some benefit, and thus to show some health need for the standard. See note 47, *supra*. For example, in the coke-oven-emissions case, the Secretary conducted such a study. The results are discussed at note 15 of our memorandum in response to the petitions in Nos. 78-918 and 78-919. But as that discussion shows, even those studies have obvious limitations.

The Secretary makes even greater uses of risk assessments when dealing with non-carcinogens. For example, in establishing the permissible exposure level for lead, the Secretary was able to assess the extent of risk, identify different populations that faced risk thresholds at different levels of exposure, and consider these factors in setting the permissible exposure level. See 43 Fed. Reg. 52952, 52960-52972 (1978). In some instances "safe" levels of exposure to non-carcinogens can be determined. The determination of safe levels, once made, can be the basis for satisfying the statutory criteria without reducing exposure to the lowest feasible levels. Here, too, however, the technique was used to identify the nature and extent of health needs rather than to balance costs against benefits.

evidence was unjustified.[56] Cf. *Permian Basin Area*

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[56] The court of appeals suggested that the Secretary await the results of animal studies before ordering reductions in exposure to benzene (Pet. App. 20a n.25). But, as the court recognized, it has not been shown that benzene causes cancer in animals. It has, however, been shown that benzene causes cancer in humans; no one disputes this. Under these circumstances, it is difficult to understand what increase in precision might be achieved by waiting for the accumulation of evidence that, by any standard, is not "available." See Pet. App. 119a-120a (discussing animal studies).

The court of appeals also concluded that some evidence now available showed that more "valid extrapolations" would become available in the future (Pet. App. 19a n.23). Aside from the obvious fact that what might become available in the future is not available now, the court of appeals' excursion into the risky business of scientific prediction is open to serious dispute; it is at odds with the record and with the Secretary's conclusions.

First, the court relied on Dr. Richard Wilson's "preliminary risk assessment" showing that only two deaths every six years would be averted by the reduction in exposure to 1 ppm. (A. 176). The Secretary, however, rejected Dr. Wilson's conclusion because: (1) Dr. Wilson conceded that the reliability of the data on which he based his "guess" (Tr. 2772; A.92) was "quite poor" (Tr. 2720); (2) Dr. Wilson gave no basis for his conclusions at the hearing (Tr. 2743, 2790-2798), and, although he agreed to supply this information to the Secretary (Tr. 2752-2753), he never did so; (3) Dr. Wilson improperly dismissed the Infante study as unreliable (Pet. App. 107a); and (4) Dr. Wilson underestimated the number of workers who are regularly exposed below 10 ppm benzene concentrations. See Pet. App. 161a-162a.

Second, the court asserted that Dr. Lawrence Partridge, a member of the staff of the Secretary's economic consultant (Arthur D. Little, Inc.), stated that his firm could "perform a cost-effectiveness analysis for the benzene standard." In fact, the Secretary's consultant stated only that his firm was generally qualified to perform cost-effectiveness studies. He did not testify that sufficient data to perform such a study existed

Rate Cases, *supra*, 390 U.S. at 776 n.40; *NAACP* v. *FPC*, 425 U.S. 662, 672 (1976) (Powell, J., concurring).

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In sum, the Secretary's position is that the toxic substances provision of OSHA neither requires nor permits him to establish exposure levels on the basis of tradeoffs, identified by cost-benefit techniques, between health benefits and costs. Even if the statute permits such a tradeoff, it does so only when the evidence to make such a decision is "available," which is not the case for benzene. This is not to say that costs and benefits play no role in the statutory scheme. They clearly do. There must be substantial evidence for concluding that a lower exposure level

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for benzene (Tr. 512). To the contrary, his economic report specifically stated the data did *not* exist with regard to benzene (Exh. 5A at 3-5).

Third, the court of appeals observed that, after the close of the record in this case, the EPA had released a preliminary report on the relationship between cancer and benzene. See *Preliminary Report on Population Risk to Ambient Benzene Exposures* (1978) (A. 14-29). The EPA, however, emphasized that its estimates were devised by "very crude methods" (A. 25). This report, moreover, was based on the data collected by Dr. Infante, who stated that, in his view, the exposure data were too imprecise to establish a dose-response relationship (Tr. 874, 927, 928, 1050, 1056, 1129-1130, 1155-1156; see also Dr. Goldstein, Exh. 75 at 2-3). The Secretary agreed with Dr. Infante. That EPA may have concluded that its risk estimate is usable for its own purposes (such as confirming that the levels of benzene now found in the ambient air pose a public health hazard) is no basis for disturbing the Secretary's judgment that the same evidence is not useful for a quite different purpose. Cf. *Universal Camera Corp.* v. *NLRB*, 340 U.S. 474, 476 (1951).

will be beneficial; here there was such evidence, as the court of appeals acknowledged (Pet. App. 18a). Risk assessment can be employed to identify safe levels of exposure for some substances (see note 55, *supra*). And the cost of compliance can be considered in at least five ways: (1) in setting regulatory priorities (see note 47, *supra*); (2) in defining what level of exposure can be achieved feasibly (see pages 56-59 and note 50, *supra*); (3) in selecting the method by which employers must achieve the lowest feasible level of exposure;[57] (4) in granting variances under which less expensive, but equally effective, methods of control can be substituted for those specified by the Secretary (see note 7, *supra*); and (5) in the course of enforcing the standards (see note 44, *supra*). Our point is not that the statute has deprived the Secretary of the flexibility necessary for the establishment of intelligent public health policy. But it has forbidden the kind of tradeoff required by the court of appeals, and the court's requirement that the Secretary produce an "estimate of expected benefits" (Pet. App. 20a), and determine by a weighing of those benefits against the cost that the regulation bears a "reasonable relationship" to quantifiable benefits, is improper.

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[57] See *South Terminal Corp.* v. *EPA*, 504 F.2d 646, 655-656, 657, 676 n.33 (1st Cir. 1974): where Congress has forbidden the EPA to balance costs against benefits under a particular statute, "[t]urning down necessary controls because they are economically burdensome is impermissible; selecting the least burdensome effective alternative simply makes good sense."

C. Any Ambiguities In The Statute Should Be Resolved In Favor Of Greater Safety

The very most that can be said for the court of appeals' approach is that the phrases "reasonably necessary or appropriate to provide safe or healthful employment" and "to the extent feasible" are arguably ambiguous. The court of appeals resolved the ambiguity by selecting a cost-benefit requirement that, in the court's view, best served the public interest. The court overlooked two principles that should have dissuaded it from resolving the perceived ambiguity as it did.

First, OSHA is remedial legislation dealing with the public health and safety. Many cases hold that ambiguities in such legislation should be resolved in favor of safety rather than, as the court of appeals held, in favor of lower costs for industry.[58]

Second, since OSHA was enacted, the Secretary has construed the toxic substances provision of 29 U.S.C. 655(b)(5) as requiring the achievement of the lowest achievable level of exposure where a safe level cannot be determined. The Secretary has promulgated eight standards regulating exposure to carcinogens and other toxic substances (see note 24, *supra*). In almost all of the eight, the Secretary has explained that no safe level of exposure

[58] See, *e.g.*, *E.I. duPont deNemours & Co.* v. *Train*, 430 U.S. 112, 133 (1977); *FPC* v. *Florida Power & Light Co.*, 404 U.S. 453, 469 (1972); *United States* v. *Seaboard Air Line R.R.*, 361 U.S. 78, 83 (1959); *Voris* v. *Eikel*, 346 U.S. 328, 333 (1953); *Tiller* v. *Atlantic Coast Line R.R.*, 323 U.S. 574, 577 n.2 (1945); *Lilly* v. *Grand Trunk Western R.R.*, 317 U.S. 481, 486 (1943).

to such substances can be determined, concluded that in such circumstances the standard must be set at the lowest achievable level, and rejected arguments that the statute requires the level of exposure to be set by reference to cost-benefit criteria.[59] The agency's experience over the course of a decade, the Secretary recently said, "has demonstrated to us the futility of applying traditional cost-benefit analysis and methodology to the workplace health context." 43 Fed. Reg. 45762, 45790 (1978) (explanation of the acrylonitrile standard).

The Secretary's consistent and well-articulated construction of the Act is entitled to substantial deference. *E. I. duPont deNemours & Co.* v. *Collins*, 432 U.S. 46, 53-54 (1977); *Miller* v. *Youakim*, No. 77-742 (Feb. 22, 1979), slip op. 18 (and cases cited therein). An agency enjoys substantial leeway when it must interpret a new statute and fashion a solution on the basis of imperfect data. *Permian Basin Area Rate Cases*, 390 U.S. 747, 777 (1968). Deference to the agency's approach is all the more appropriate where, as here, the agency's interpretation is supported by the agency's practical experience in implementing the statute, see *American Trucking Associations* v. *Atchison, Topeka & Santa Fe Ry.*, 387 U.S. 397, 416 (1967); *Skidmore* v. *Swift & Co.*, 323

[59] See especially 39 Fed. Reg. 35890, 35892 (1974) (vinyl chloride); 41 Fed. Reg. 46742, 46751 (1976) (coke oven emissions); 43 Fed. Reg. 27350, 27378-27389 (1978) (cotton dust); 43 Fed. Reg. 52952, 52963 (1978) (lead dust); 43 Fed. Reg. 45762, 45790 (1978) (acrylonitrile). See also 37 Fed. Reg. 11318 (1972) (asbestos dust); 39 Fed. Reg. 3756, 3758 (1974) (14 selected carcinogens).

U.S. 134, 140 (1944), and the statute in question is a complex one requiring scientific expertise, see *Train* v. *Natural Resources Defense Council, Inc.*, 421 U.S. 60, 87 (1975), *E. I. duPont deNemours & Co.* v. *Train*, 430 U.S. 112, 135 n.25 (1977). Certainly the Secretary's construction is "sufficiently reasonable to preclude the court of appeals from substituting its judgment for that of the Agency." *Train* v. *Natural Resources Defense Council, Inc.*, *supra*, 421 U.S. at 87.

II

THE SECRETARY WAS NOT REQUIRED TO WAIT FOR MORE EVIDENCE BEFORE RESTRICTING DERMAL CONTACT WITH BENZENE-BEARING LIQUIDS

The Secretary determined that dermal contact with liquids containing benzene creates a risk of cancer, and he accordingly ordered workers to wear protective clothing to avert that risk (see pages 25-28, *supra*). The court of appeals held that the Secretary's decision that benzene is absorbed through the skin is supported by substantial evidence (Pet. App. 25a). Despite the statutory command in 29 U.S.C. 655(f) that "[t]he determinations of the Secretary shall be conclusive if supported by substantial evidence" and despite the command in 29 U.S.C. 655(b)(5) that toxic substances regulations shall be based on the best "available" evidence, the court set aside the dermal contact rules on the ground that other evidence that might become available in the future would throw more light on the subject.

The court of appeals was wrong for several reasons. First, in setting aside a standard despite the presence of substantial evidence, the court disregarded 29 U.S.C. 655(f). Second, in considering the prospect of a study not in the record, the court overlooked the rule that "review of administrative decisions is to be confined to 'consideration of the decision of the agency * * * and of the evidence on which it was based'." *FPC* v. *Transcontinental Gas Pipe Line Corp.*, 423 U.S. 326, 331 (1976), quoting from *United States* v. *Carlo Bianchi & Co.*, 373 U.S. 709, 714-715 (1963). Third, the court transgressed 29 U.S.C. 655(b)(5), which limits decisions to the "available" evidence.

The court of appeals' instruction to the Secretary to await the production of additional evidence could be justified only if the phrase "best available evidence" in Section 655(b)(5) means "the best evidence capable of being produced." But the legislative history of the "best available evidence" rule, which we discuss at pages 60-61, *supra*, shows that the phrase was intended by Congress to mean "the best evidence in existence," rather than "the best evidence capable of being produced." Congress was aware of the potential for paralysis that medical disputes could introduce into the administrative process. There is always more evidence just around the corner. Congress intended the "best available evidence" approach to free the Secretary from the grip of claims that he should wait for just one more study, sure to be conclusive. As the House Committee put the matter

(Leg. Hist. 848): "The Committee feels it is vital that when the Secretary sets an occupational health standard he do so on the basis of the best available professional evidence; it is not intended that the Secretary be paralyzed by debate surrounding diverse medical opinions." By insisting that the Secretary wait for just one more study—which the court of appeals thought would be definitive—the court of appeals introduced the very paralysis that Congress wanted to avoid.

The circumstances of this case well show the importance of the "best available evidence" rule and the difficulties caused by insisting on the accumulation of more evidence. The court of appeals held that the agency should have obtained and considered the results of tests using radioactive benzene. The court said that these tests would have provided conclusive answers in six to twelve weeks to the question whether benzene is absorbed through the skin, as well as several other allied questions (Pet. App. 25a-26a). The agency thus violated, in the court's view, the directive in Section 655(b)(5) that standards be based on "research, demonstrations, experiments" and "the latest available scientific data in the field." The court did not deny that the record is replete with "research," "demonstrations," and "experiments" on the skin-absorption issue and included the best scientific evidence available at the time of the rulemaking proceeding.[80] The court held, however, that Section 655(b)(5) requires the Secretary "to acquire" (Pet. App. 27a) a radioactive benzene study before issuing any dermal prohibition and protective clothing requirement.[81]

[80] The standard was in part based on the fact that benzene causes dermatitis, which, aside from its own health effects, increases the risk that benzene will be absorbed through the damaged skin. The court dismissed the agency's theory that dermal contact causes dermatitis as a "post hoc rationalization" (Pet. App. 22a). This was hardly so; this risk was specifically relied on by the agency (*id.* at 193a).

[81] Respondent Rubber Manufacturers Association has contended that the Secretary erred in refusing to reopen the record and stay the standard for 180 days while Dr. Maibach conducted the radioactive benzene tests. Although the court below did not discuss the question, the Secretary did not err in refusing the request. This Court has never reversed a refusal by an agency to reopen an administrative record except on a showing of abuse of discretion. See *Bowman Transportation, Inc.* v. *Arkansas-Best Freight System, Inc.*, 419 U.S. 281, 294-295 (1974). Here there was no abuse of discretion. The statute itself put industry on notice that toxic substances are subject to regulation, and it was common knowledge that benzene is toxic. The central question for industry, then, was not whether the Secretary would begin to investigate exposure to benzene, but how soon he would do so (given the substantial numbers of other toxic substances subject to regulation). Industry could have begun the process of research as soon as the statute was enacted; it did not need to wait until the initial notice of rulemaking. And questions concerning the extent of absorption of benzene into the body through exposed surfaces were obvious candidates for research. The Secretary's notice of rulemaking, in any event, clearly advised industry that the proposed standard would include a prohibition against dermal contact with liquid benzene. All interested parties were invited to present their views at the rulemaking hearing. Dr. Maibach appeared on behalf of the American Petroleum Institute and presented his views. Industrial users of liquid benzene also presented their views (Exhs. 6-48, 6-59). Eventually the administrative record

The requirement that the standard be based on the "latest," "best," "available" evidence was clearly satisfied in this case. There was no radioactive benzene study in existence, although the industry had ample time to prepare one. And, as things turned out, there was no reason to wait.

Dr. Maibach's preliminary report was supplied to the agency for the first time in January 1979. It supports the Secretary's decision because it shows that benzene is absorbed through the skin and thus confirms the Secretary's conclusion that dermal contact with benzene poses a cancer risk. The attempt to perform a radioactive benzene test also illustrates the pitfalls in setting aside a standard based on the speculation that evidence can be created readily. Dr.

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was closed, and the Secretary concluded that skin absorption of benzene posed a cancer risk and issued a standard that prohibited dermal and eye contact with liquid benzene. The request to reopen came several months thereafter during a later proceeding directed solely to the issue whether the standard should be amended to exclude workplaces where the only exposure resulted from certain liquids with trace amounts of benzene. The request was not accompanied by the actual evidence sought to be added but was, in reality, merely a request that the standard be stayed for 180 days while Dr. Maibach conducted the very test that the parties were free to conduct and submit a year earlier during the rulemaking proceeding. The agency's representative refused the request on the ground that it would be inconsistent with the narrow scope of the amendment proceeding (Amend. Tr. 20-21; A. 185-186). He explained that the agency would consider such study once it was available. But the agency would not defer the standard for 180 days to await a study whose "results could not possibly be known at this time" (*ibid.*). This decision was not an abuse of discretion.

Maibach testified that the radioactive benzene tests not only would determine whether benzene is absorbed through the skin but also would answer a number of other issues, such as the effect of repeated applications on the skin, and the effect of temperature variations. The court of appeals was influenced by the prospect that "conclusive" answers to so many questions were "readily" available in a short time through a simple study (Pet. App. 26a). But the time proved to be not-so-short. Dr. Maibach's "preliminary" results were received by the Secretary one-and-a-half years after Dr. Maibach testified that his study could be completed in six to twelve weeks.[62] The results proved to be not-too-conclusive.[63] Moreover, Dr. Mai-

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[62] Dr. Maibach testified on August 3, 1977. In May 1978 the Secretary was advised by respondent Rubber Manufacturers Association that Dr. Maibach had begun his tests; the Association similarly advised the court of appeals at oral argument in June 1978 (Pet. App. 27a n.27). The preliminary report of Dr. Maibach was submitted in January 1979 in the form of an appendix to the brief of the Rubber Manufacturers Association in opposition to the petitions for certiorari. The preliminary report states that additional studies will have to be conducted. Perhaps the additional studies will be furnished as an appendix to another brief during the coming months.

[63] As to the rate of absorption, the Maibach study is subject to serious question. The study was conducted in a manner that underestimates the rate of absorption. First, the subjects were exposed to only a single dose of benzene (Rubber Mem. in Opp. App. 7a), whereas in real life some employees are exposed repeatedly to liquids containing benzene. Dr. Maibach testified in 1977 that the number of doses might well make an important difference (Tr. 2467; A. 63). Second, much of the dose applied in the Maibach study would have evaporated

bach's study did not address any issue except to confirm the Secretary's conclusion that benzene may be absorbed through the skin and to suggest that the rate of absorption depends on the amount applied.[64]

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from the skin, thus reducing the amount of benzene available for penetration. Dr. Maibach testified in 1977 that benzene is very volatile and evaporates rapidly (Tr. 2468; A. 63). The Maibach subjects were kept outdoors, which would have accelerated evaporation. Third, in the Maibach study liquid benzene was applied to the forearm of a rhesus monkey; the forearms of rhesus monkeys and humans may not be comparable for absorption purposes. Fourth, the rate of absorption through human skin varies greatly with the part of the body, as Dr. Maibach testified (Tr. 2466, 2480; A. 62, 71). Studies on the rate of absorption through the forearm thus may not indicate the usual rate of absorption. Fifth, the rate of absorption usually increases with the temperature (Tr. 2479; A. 70). The study does not state the temperature at which the subjects were maintained. Sixth, the Maibach study, which relies on a single application of benzene to the test subjects, does not take into account the fact that repeated contact with benzene can blister the skin and reduce its ability to prevent penetration. In 1977 Dr. Maibach testified that penetration normally is greater through damaged skin than undamaged skin (Tr. 2469; A. 63). Seventh, Dr. Maibach based his "preliminary judgment" about the comparative amount of benzene absorbed through the skin and inhaled through the lungs on a computation provided by respondent Rubber Manufacturers Association (Rubber Mem. in Opp. App. 10a-11a). Dr. Maibach stated that "[f]urther experiments are necessary in order to draw conclusions as to the comparative amount of benzene absorbed" (*id.* at 10a). The Maibach study itself admits several of these limitations.

[64] Dr. Maibach concluded that not very much benzene is absorbed through the skin. Even if the conclusion about the rate of absorption were reliable (but see note 63, *supra*), it would not cast doubt on the dermal contact prohibition. Because there is *some* absorption, because this adds to whatever

Dr. Maibach proposed further experiments to tackle the additional issues that the court of appeals thought would be resolved in Dr. Maibach's initial effort.

This train of events illustrates our point that industry often will be able to point to toxicological research that allegedly will provide conclusive answers to scientific uncertainties. It illustrates the mischief that can be caused when health standards are postponed in the hope that one more study will settle the matter. These considerations underscore Congress' wisdom in requiring the Secretary to consider only available evidence in discharging his responsibility to protect the health of employees.[65] If the Secretary were required to wait until the evidence had been supplied—however long that might take—the power to control the timing of new regulations would be effectively transferred from the Secretary to the affected parties, who would have every incentive to delay.

Finally, the Secretary did not violate the requirement that the standard be based on "research, demonstrations, experiments, and such other informa-

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is inhaled, and because there is no known safe level of exposure, the Secretary was required to adopt the lowest feasible level of exposure. It is unquestioned that the use of protective clothing to prevent dermal or eye contact with benzene-bearing liquids is feasible.

[65] Of course, if, after the Secretary has promulgated a standard, new evidence comes to light casting doubt on the wisdom of any standard, then any interested person may ask the Secretary to make appropriate revisions in the standard. 29 U.S.C. 655(b)(1).

tion as may be appropriate." The dermal prohibition *was* based on research, demonstrations and experiments. Moreover, this language permits the Secretary to determine the extent to which it is "appropriate" to acquire research, demonstrations, and experiments or other information in setting standards.[66] This discretion, entrusted as it is to the agency Congress believed best capable of making the expert judgment required, should be set aside by a court only on the clearest abuse of discretion. No such abuse exists here.[67]

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[66] The Senate committee, which added this language, made it clear that the phrase "as may be appropriate" modifies not only "other information" but also "research, experiments [and] demonstrations": "The committee intends that [the] standards promulgated under section 6(b) shall represent feasible requirements, which, *where appropriate*, shall be based on research, experiments, demonstrations, past experience, and the latest available scientific data." Leg. Hist. 147 (emphasis added).

[67] Although the Secretary has no independent research capability, 29 U.S.C. 669(c) permits him to contract with private organizations for "studies" to carry out his responsibilities under the Act. The extent to which the Secretary contracts for independent studies before issuing a standard is a decision concerning "how best to allocate its resources," which, at most, is reviewable only for an abuse of discretion. *Moog Industries, Inc.* v. *FTC*, 355 U.S. 411, 414 (1958); *Wisconsin* v. *FPC*, 373 U.S. 294, 313-314 (1963). Cf. *FPC* v. *Transcontinental Gas Pipe Line Corp., supra*, 423 U.S. at 333; *Utah Fuel Co.* v. *National Bituminous Coal Commission*, 306 U.S. 56, 61 (1939); *Endicott Johnson Corp.* v. *Perkins*, 317 U.S., 501, 506-507 (1943); *CAB* v. *Hermann*, 353 U.S. 322, 323 (1957); *FCC* v. *Schreiber*, 381 U.S. 279, 290 & n.17 (1965); *Vermont Yankee Nuclear Power Corp.* v. *Natural Resources Defense Council, Inc.*, 435 U.S. 519, 524-525 (1978). NIOSH, the only agency with independent research capability under the Act (29 U.S.C. 669), concluded that benzene is readily absorbed through the skin (Pet. App. 193a); and respected industrial hygienists recommended that dermal contact be prevented (*ibid.*). These considerations amply support the Secretary's decision not to wait for or acquire still another study.

CONCLUSION

The judgment of the court of appeals should be reversed, and the case should be remanded with instructions to dismiss the petitions for review.

Respectfully submitted.

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APPENDIX

LEGISLATIVE HISTORY OF 29 U.S.C. 655(b)(5)

No provision similar to Section 655(b)(5) appeared in any of the bills initially introduced in either the House or the Senate. All but a few of the many bills contemplated that national consensus standards and established federal standards would be adopted as national health standards under the Act; they permitted the Secretary (or a board) to issue new standards but did not set out any criteria for these new rules. See Leg. Hist. 1-140, 599-830.

The House Committee on Education and Labor, the first committee to report any bill, drafted the first precursor of the present Section 655(b)(5):

> The Secretary, in promulgating standards under this subsection, shall set the standard which most adequately assures, on the basis of the best available professional evidence, that no employee will suffer any impairment of health, or functional capacity, or diminished life expectancy even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.

Leg. Hist. 943. This provision (Section 6(b)(5) of the bill) was designed to deal with the deficiencies of national consensus standards and established federal standards. The House report stated (*id.* at 848):

> During the hearings, the Committee considered the degree to which it would rely upon the use of national consensus standards in the ad-

ministration of an Occupational Safety and Health Act. It determined that these standards could not be given preferential treatment, since their credibility is suspect on two grounds: first, a private organization is susceptible to the pressures of commercial trade association interests, and second, consensus standard organizations have been slow in the development and updating of present safety standards.

* * * * *

Voluntary standards set by the consensus method represent the lowest common denominator of change in the status quo that is necessary to achieve acceptance. Now that we have chosen the force of law to command acceptance of safety and health regulations, this method should not apply.

The committee felt it vital that the Secretary be allowed to overcome these deficiencies by promulgating standards that would "insure that no employees will suffer any impairment of health, functional capacity or diminished life expectancy from regular exposure to a hazard" (*ibid.*).

The Senate Committee on Labor and Public Welfare later reported a similar bill (S. 2193) with a requirement for new standards providing (Leg. Hist. 242):

> The Secretary, in promulgating standards under this subsection, shall set the standard which most adequately and feasibly assures, on the basis of the best available evidence, that no employee will suffer any impairment of health or functional capacity, or diminished life expectancy even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of such standards shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws.

Like its House counterpart, this provision was not limited to toxic materials or harmful physical agents; it applied to all new standards set by the Secretary. The Senate report also emphasized that "so far as possible" standards were to assure maximum health protection:

> Such standards should be directed at assuring, so far as *possible*, that no employee will suffer impaired health or functional capacity, or diminished life expectancy, by reason of exposure to the hazard involved, even though such exposure may be over the period of his entire working life.

Id. at 147 (emphasis added).[1]

The Senate bill, however, substituted in Section 6 (b)(5) the phrase "which most adequately and feas-

[1] Like the House report, the Senate report also recognized that many of the consensus standards would be out-of-date and that the Secretary would need to update them through modifications and to promulgate new standards where none existed. *Id.* at 146-147.

ibly assures" for the House bill's "which most adequately assures." *Id.* at 242, 943. Senator Javits, a member of the committee, explained that the adoption of the feasibility requirement was "an improvement over the [House] bill, which might be interpreted to require absolute health and safety in all cases, regardless of feasibility * * *" Leg. Hist. 197, 418. (No one suggested at any time that the phrase "reasonably necessary or appropriate," which appeared in the definitional sections of both bills, already precluded economically infeasible standards.)

Notwithstanding the feasibility requirement, this provision was criticized on the Senate floor as "unrealistic," as imposing an "impossible" standard requiring "absolute" safety. Leg. Hist. 345, 367, 401, 423, 480-481. During the Senate debate, Senator Dominick offered an amendment that would have deleted the principal language of Section 6(b)(5) and substituted (Leg. Hist. 242, 365-367):

> Development of standards shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of health and safety protection for employees, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws.

Senator Dominick explained that his amendment would eliminate "the requirement in section 6(b)(5) that the Secretary will establish occupational safety and health standards which most adequately

and feasibly assure to the extent possible that *no* employee will suffer *any* impairment of health or functional capacity, or diminished life expectancy." *Id.* at 367 (emphasis in original). He proposed to do this because the Committee's bill "could be read to require the Secretary to ban all occupations in which there remains *some* risk of injury, impaired health, or life expectancy. In the case of all occupations, it will be impossible to eliminate all risks to safety and health. Thus, the present criteria could, if literally applied, close every business in this nation. In addition, in many cases, the standard which might most 'adequately' and 'feasibly' assure the elimination of the danger would be the prohibition of the occupation itself." *Ibid.* (emphasis in original).

Consideration of the amendment was delayed, however, while an attempt was made by the Nixon Administration to substitute its own bill for the Committee's bill. Senator Williams, the principal sponsor of S. 2193, opposed the substitution on the ground, among others, that the Administration's bill contained no provision such as Section 6(b)(5):

> Under the committee bill, the Secretary is required to set the standard which most adequately and feasibly assures that no employee will suffer any impairment of health or functional capacity, or diminish life expectancy, even if such employee has regular exposure to the hazard for the period of his working life.
>
> * * * * *
>
> The substitute bill is completely silent on the matter of providing statutory guidelines for the

promulgation of standards—a silence that by itself makes the substitute seriously deficient for the interests of both industry and labor.

The worker is entitled to know that standards in the workplaces are geared to overcoming safety and health hazards that are shortening his life. If he cannot have the assurance that criteria for standards are based on this consideration, he will have a program of no value to him.

Leg. Hist. 432.

The sponsor of the substitute measure, Senator Dominick, acknowledged this difference in the two bills. He argued, however, that the Administration's bill was an improvement because it would be "totally impossible" to make sure that employees "will not have any risk to his life for the rest of his life." Leg. Hist. 423. The substitute was defeated. *Id.* at 449-450.

A compromise was then reached concerning the scope of Section 6(b)(5). Senator Dominick modified his amendment to insert the present wording of 29 U.S.C. 655(b)(5). This restricted the reach of Section 6(b)(5) to "standards dealing with toxic materials or harmful physical agents." Immediately before passage of the modified amendment, Senator Dominick explained that the intent was to limit the mandate in the section to toxic substances and harmful physical agents (Leg. Hist. 502). He and Senator Williams then explained the amendment as follows:

Mr. Williams of New Jersey. * * * As I understand this amendment, it will provide continued direction to the Secretary that he shall be required to set the standard which most adequately and to the *greatest* extent feasible assures, on the basis of the best available evidence, that no employee will suffer any material impairment of health of functional capacity even if such employee has continual exposure to the hazard dealt with for the period of his working life.

* * * * *

Mr. Dominick. * * * [W]hat we are doing now is to say that the Secretary has got to use his best efforts to promulgate the *best* available standards, and in so doing, that he should take into account that anyone working in toxic agents or physical agents which might be harmful may be subjected to such conditions for the rest of his working life, so that we can get at something which might not be toxic now, if he works in it a short time, but if he works in it the rest of his life it might be very dangerous; and we want to make sure that such things are taken into consideration in establishing standards; is that correct?

Mr. Williams of New Jersey. That is exactly correct.

Id. at 502-503 (emphasis added).[2] The nature of the compromise is clear: Senator Dominick and his supporters relented by allowing some standards to be set without regard to cost, if feasible, while Senator

[2] The only other modification was to change the phrase "most adequately and feasibly assures" to "most adequately assures, to the extent feasible." No explanation was given for the shift in emphasis, but the shift suggests a preference for health protection over cost.

Williams and his supporters relented by restricting the scope of Section 6(b)(5) to special hazards (to be substances and harmful physical agents) rather than (as before) to all hazards.

The amendment, as modified, was then accepted. Leg. Hist. 503. The Senate then passed the entire bill. *Id.* at 526-528. A few days later, however, the House enacted the Administration's bill, which omitted any such requirement. *Id.* at 1112-1118, 1121.[3] In the conference, the House receded and accepted Section 6(b)(5) without change. An amendment was added to provide for temporary variances for those unable to meet the standards required by Section 6(b)(5). "Economic hardship," however, "is not to be a consideration for the qualification for a temporary extension order." Leg. Hist. 1188 (House Conference Report). The conference bill was passed by both the Senate and the House. *Id.* at 1150, 1225-1228. Significantly, at no time during the consideration of Section 6(b)(5) (or at any other time) was any suggestion made that the Secretary must estimate the number of lives that the proposed standard will save and determine whether the saving is worth the cost of the standard.

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[3] The bill reported to the House by the committee had contained such a proviso (but without any feasibility condition) (see page 1a, *supra*), but during floor debate it was criticized once again as "unrealistic" and as an "impossible burden" on employers. Leg. Hist. 1053, 1087-1088. Once again, such criticism would have been unwarranted if the phrase "reasonably necessary or appropriate" already moderated the scope of permissible standards.

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1978

INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*,
Respondents;

and

RAY MARSHALL, SECRETARY OF LABOR,
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

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Nos. 78-911 & 78-1036

IN THE

Supreme Court of the United States

OCTOBER TERM, 1978

INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*,
Respondents;

and

RAY MARSHALL, SECRETARY OF LABOR,
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF FOR RESPONDENTS

QUESTION PRESENTED

Whether the court below correctly set aside OSHA's[1] reduction of the benzene exposure standard from 10 parts per million ("ppm") to 1 ppm on the grounds that OSHA violated: (i) the standard-setting requirements of the Act, and (ii) the requirement that there be "substantial evidence" supporting OSHA's "determination" that a reduction to 1 ppm would produce "appreciable benefits."

[1] Sections 2(b)(3) and 6(b) of the Occupational Safety and Health Act ("Act" or "OSH Act") authorize the Secretary of

(footnote continued on next page)

COUNTERSTATEMENT OF THE CASE[2]

In an effort to portray the decision below as extreme and impractical, OSHA exaggerates the court's holding as requiring it to perform a mathematically-precise "cost-benefit" analysis. OSHA asserts that the court's decision would require it in every case to ascertain "the number of *lives* (and other health benefits) that the standard will save and determine whether their *value*" is "*commensurate*" with the control costs imposed. OSHA Br. 32, 35 (emphasis added). OSHA alludes to this supposed requirement of "cost-benefit" balancing in its "Question Presented" (*id* 2.) and repeatedly throughout its

(footnote continued from previous page)
Labor to set occupational safety and health standards. 29 U.S.C. §§ 651(b)(3) & 655(b). The Secretary has delegated this authority to the Assistant Secretary for Occupational Safety and Health, the head of the Occupational Safety and Health Administration ("OSHA"). 41 Fed. Reg. 25059 (June 22, 1976).

[2] This Brief adopts the abbreviations for references to the record and legislative history set forth at n.1 of the Brief for the Federal Parties ("OSHA Br."). The opinion of the court of appeals, *American Petroleum Institute* v. *OSHA*, is reported at 581 F.2d 493, and is reproduced at Pet. App. 1a-33a. The benzene standard and OSHA's accompanying explanation appear at 43 Fed. Reg. 5918-70, and are reproduced at Pet. App. 34a-252a.

The principal statutory provisions upon which this Brief relies are set forth in full in Addendum A. In addition, a chronological review of the legislative history of the standard-setting provisions of the Act is contained in Addendum B ("Add. B"), and Addendum C ("Add. C") briefly summarizes the practices of other federal health and safety agencies as they bear on the issues in this case.

Respondents concur in and support the separate brief filed today on the "dermal exposure" issue.

Brief.[3] But in fact OSHA's distorted reading finds little support in either the court's opinion or the record of this case.

The crux of the holding below is that the Act does not permit OSHA to disregard the evidence and act arbitrarily when "substantial evidence does not support" the agency's determination that the benefits of its action are "likely to be appreciable." Pet. App. 18a (581 F.2d at 503). In essence, the court ruled that OSHA failed to comply with the Act when it made its "appreciable benefits" determination based upon nothing more than a tautological assumption that "exposures to low levels of toxic materials would be safer than exposure to higher levels." *Id.* 18a (581 F.2d at 503). In the court's view, this "assumption" could not override the record evidence showing that the health benefits, if any, of OSHA's lowered standard were likely to be insignificant. *Id.* 19a (581 F.2d at 504).

To cure the agency's failure to base its standard on "substantial evidence of discernible benefits" (Pet. App. 18a (581 F.2d at 503)), the court required—not that OSHA "conduct an elaborate cost-benefit analysis"—but only that, as part of its decision-making process, OSHA consider a "rough but educated estimate[] of the extent of benefits expected from reducing the permissible exposure level from 10 ppm

[3] *See, e.g.*, OSHA Br. 22-23, 33-36, 38-42, 48-49, 51-52, 54-56, 60, 68, n. 55, 73.

to 1 ppm." *Id.* 17a, 21a (581 F.2d at 503, 504).[4] Without such "a rough but educated estimate" of the risks prevented (*i.e.*, the benefits), OSHA lacked "the required support" to show "reasonable necessity for the standard promulgated." *Id.* 21a (581 F.2d at 505).

The reasons why the law requires OSHA to follow such a process in setting standards are obvious. Benzene is only one of a great many potential occupational hazards posing vastly differing risks. Regarding the risk of cancer alone, the National Institute for Occupational Safety and Health ("NIOSH") has identified nearly 2,000 suspect occupational carcinogens,[5] and OSHA itself has targeted almost 300 "Category I" carcinogens for standards comparable

[4] The court's holding goes no further than, and perhaps not as far as, the regulatory practices of other federal health and safety agencies, including the Environmental Protection Agency, the Food and Drug Administration, the Nuclear Regulatory Commission, the National Highway Traffic Safety Administration, and, on occasion, even OSHA itself. *See* pp. 20, 29-30, 73-75, *infra;* Add. C 8c-14c, *infra*. Significantly, the President's Council on Wage and Price Stability recommended that OSHA follow a closely similar process in this very case. A. 124, 126, 129-31. *See* pp. 18-19, 20, *infra*.

[5] NIOSH has published a list of 2,415 potential occupational carcinogens, of which 1,905 substances "were selected on the basis of reported neoplastic or carcinogenic effects." NIOSH, SUSPECTED CARCINOGENS: A SUBFILE OF THE NIOSH REGISTRY OF TOXIC EFFECTS OF CHEMICAL SUBSTANCES, 2d Edition, Herbert E. Christiansen (Ed.), HEW Publication No. (NIOSH) 77-149 (December 1976). Apart from great differences in the levels and extent of worker exposure to these substances, their carcinogenic potency can vary by as much as a factor of one million. *See* Add. C 3c-4c, *infra*.

to the one at issue in this case.[6] It defies not only the law, but common sense as well, for OSHA to blind itself to these realities and, instead, to regulate each hazard it identifies simply by picking an exposure limit and then proving that those affected can bear the cost and still survive financially. Yet, this is precisely what OSHA did in the case of benzene. *See* pp. 17-18, 21-24, 31, *infra*.

Given the magnitude of the job ahead, now is no time for OSHA to "bury[ ] its head in the sand." A. 47. What is needed for benzene (and other substances) is for OSHA to assemble, consider, and evaluate *all* the available scientific data, including evidence on the degree of risk reduction (*i.e.*, the benefits) expected to result from more stringent regulation. For unless OSHA carefully and systematically evaluates all of the available evidence, those most adversely affected in the long run will be the workers (who will receive less overall health protection) and the public (which ultimately will bear the cost of needless regulations).

[6] *See* OSHA's *Proposed Rule for the Indentification, Classification, and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk*, 42 Fed. Reg. 54148 (October 4, 1977) ("OSHA Proposed Cancer Policy"). Under these proposed regulations, toxic substances would be classified according to the evidence suggesting that they are carcinogens. *Id.* 54168-74. Each substance classified as a "Category I" carcinogen would automatically be the subject of what OSHA calls a "full blown" standard reducing exposure to the "lowest feasible level," regardless of any differences in the carcinogenic potency, extent of exposure, or costs of controlling the substance in question. *Id.* 54170-71. OSHA has tentatively concluded that 269 of the approximately 2000 substances on NIOSH's "Suspect Carcinogens" list are "Category I" carcinogens. *See* OSHA Press Release, USDL 78-625, July 14, 1978 and attached lists (Exh. 132 in OSHA Docket H-90). *See also* Add. C 2c-4c, *infra*.

A. Background of the Benzene Standard

Few chemicals are more common in industry or society than benzene. Although OSHA alludes to benzene's commercial significance (OSHA Br. 9 n. 8), it neglects to mention that benzene is naturally present in water supplies, animal and plant matter, many foods[7] and, most significantly, in crude oil, where it occurs in amounts from trace levels to more than one percent by liquid volume.[8]

Benzene first appeared as a commercial product in the early 1800's. Today, it is manufactured in the petroleum refining process (and to a lesser extent, in the coal-coking process) for use in the petrochemical industry and in the production of gasoline. Pet. App. 6a (581 F.2d at 497-98). Countless intermediate and final products, including most plastics, as well as artificial fibers and rubber, are derived from benzene. *Id.* 6a (581 F.2d at 498), 69a.

Because benzene has been exhaustively studied, far more is known about its health effects than most other chemicals.[9] Short-term exposure to high benzene concentrations (over 250 ppm) can result in

[7] Testimony of Dr. Herman Kraybill (National Cancer Institute) Exh. 84.B-18 app. at 2-3, Tr. 1176, 1192-94; Testimony of Edward Baier (NIOSH), Exh. 84.A at 7, Tr. 749-50; 1132; Mobil Research and Development Corp. Memorandum, Exh. 117.

[8] Testimony of American Petroleum Institute ("API") witness Harold A. Galloway, Exh. 115.A-4 at 2-3, 5-7, Tr. 1465; testimony of API witness R.J. Comeaux, Exh. 115.A-2 at 2-4.

[9] A single report by OSHA witness Dr. Bernard Goldstein contains nearly a thousand scientific literature references regarding the health effects of benzene. Goldstein, *A Critical Evaluation of Benzene Toxicity* (Exh. 43.B). Many additional references were cited by other witnesses or listed in OSHA's Federal Register notice. *See, e.g.*, Exh. 2.

"acute" reactions ranging from headache to rapid death at levels of about 20,000 ppm. Pet. App. 6a (581 F.2d at 498), 79a-80a. Long-term exposure to levels above the present 10 ppm standard can produce "chronic" toxicity, including bone marrow depression, aplastic anemia, pancytopenia and chromosomal changes. *Id.* 7a (581 F.2d at 498). OSHA's current 10 ppm standard, adopted in 1971 (29 C.F.R. § 1910.1000 Table Z-2), was addressed primarily to these non-malignant effects.[10]

For many years, there has been evidence (including unsystematic population studies and case

[10] Despite the finding of the court below that the benzene standard was clearly designed to deal with the leukemia hazard of benzene exposure (Pet. App. 9a, 22a-23a n. 26, (581 F.2d at 499, 505 n.26)), OSHA's lawyers make a belated effort here to suggest that the standard should be sustained on the basis of benzene's non-malignant effects. OSHA Br. 19-20, 21 n.25. The record, however, shows that such effects played no role in the development of OSHA's standard.

The opening sentence of OSHA's Federal Register notice acknowledges that "[t]his standard is based on a determination ... that the available scientific evidence establishes that employee exposure to benzene presents a cancer-hazard—specifically, the hazard of developing leukemia." Pet. App. 67a. From the outset of the OSHA hearings, leukemia—not the non-malignant effects of benzene—was clearly the issue. Not even indirectly did OSHA's proposal invite comment on other effects; instead, OSHA said its proposal was "based on" leukemia, and that it was *because* the current standard was based on other effects that it "does not ... provide protection now shown to be necessary." 42 Fed. Reg. 27452, 27466 (Exh. 4). Moreover, fresh reassessments of all the available evidence by NIOSH (in 1974) and the American Conference of Governmental Industrial Hygienists (in 1976) have reaffirmed that OSHA's 1971 10 ppm standard is more than adequate to protect against these non-malignant effects. Exhs. 2-3, 89.A.

reports dating back as far as 1897),[11] that exposure to high benzene concentrations (in excess of 100 ppm) can cause leukemia.[12] None of these studies or reports, however, associated benzene concentrations below 100 ppm with the development of leukemia.

Despite the reports linking high benzene concentrations with leukemia, major scientific reviews of the evidence accumulated through 1976 were nearly unanimous in finding no need to revise the existing 10 ppm standard. NIOSH's 1974 Criteria Document for benzene (Exh. 2-4) recommended a 10 ppm exposure limit, which NIOSH termed a "conservative limit" designed to "prevent all adverse effects

[11] Pet. App. 99a. Many scientists believed that high-level benzene exposure might be associated with leukemia even before adoption of the current 10 ppm standard in 1971. *See, e.g.*, Hunter (Exh. 2-74); Cronkite (Exh. 2-26); Malory (Exh. 2-9); Browning (Exh. 2-31); Tareef (Exh. 2-28).

[12] For example, Dr. Muzaffer Aksoy, a principal medical witness for OSHA at the hearings, reported a two-fold excess incidence of leukemia among workers employed in unhygienic and poorly-ventilated Turkish shoe shops where benzene exposures ranged from 150-650 ppm. Testimony of Dr. Muzaffer Aksoy, Exh. 60 at 4-5; Tr. 157, 185. Dr. Aksoy repeatedly conceded that he had not observed leukemia in workers exposed to benzene levels under 100 ppm. Tr. 189, 200, 202, 260.

Similarly, Dr. Enrico Vigliani reported a twenty-fold excess incidence of leukemia among Italian rotogravure workers exposed to benzene concentrations "between 200 and 400 ppm, with peaks up to 1,500 ppm," and among Italian shoe workers where "the concentration ranged from 25-600 ppm, but mostly around 200-500 ppm." Vigliani, *Leukemia Associated With Benzene Exposure*, 271 ANN. N.Y. ACAD. SCI. 143, 144-45 (1975) (Exh. 2-49).

including leukemia from benzene exposure."[13] NIOSH's view was later confirmed by the National Academy of Sciences.[14]

In the fall of 1976, the conclusion previously reached by NIOSH and the National Academy of Sciences was reaffirmed by the International Workshop on the Toxicology of Benzene, an international conference of experts which endorsed a 10 ppm exposure limit for the following reasons:

> The Workshop discussed but could not agree on whether there was a concentration below which there would be no leukaemogenic effect clearly attributable to benzene. *Despite this inability to exclude the possible induction of leukaemia at benzene exposures below 10 ppm, it was agreed that such a case would be a rare occurrence.*

Exh. 17 at 7 (emphasis added).

[13] Memorandum of Dr. Herbert E. Christiansen (NIOSH) (November 13, 1974) (Exh. 32.B). In 1976, NIOSH issued Revised Criteria which recommended that the OSHA standard be reduced. Exh. 2-5. NIOSH's revised recommendation, however, relied primarily on a series of University of North Carolina and Harvard epidemiologic studies (*id.* 1) which the National Academy of Sciences (Exh. 2-4 at 13), the authors of the studies (Exh. 161 at 2, Tr. 3114-15), and later OSHA itself (Pet. App. 112a), all found to be inconclusive. Indeed, OSHA itself refused two 1976 petitions, one by NIOSH based on its Revised Criteria (Exh. 2-6), and a second by the United Rubber Workers ("URW") (Exh. 2-42), requesting immediate reduction of the standard. OSHA denied the URW request outright (Exh. 2-43), and its only response to NIOSH was the publication of "voluntary guidelines recommending observance of a 1 ppm limit." Exh. 2-44.

[14] Exh. 2-4 at ii. This is the same 1976 report by the National Research Council (the principal operating agency of the National Academy of Sciences) that OSHA erroneously

(footnote continued on next page)

This conclusion of the International Workshop reflects the results of years of scientific investigation and practical experience. Although hundreds of thousands of workers and tens of millions of other persons, including motorists who purchase gasoline,[15] are and have been exposed to small amounts of benzene for many years, there is no evidence of an increased incidence of leukemia even among the workers (about 30,000, by OSHA's estimate)[16] who are exposed to benzene concentrations up to 10 ppm under the current standard. *See* pp. 13-17, *infra*.

B. The Proceedings Before OSHA

1. Misinterpretation of the Infante Study and issuance of an emergency temporary standard

It was on the basis of the April 1977 Infante Study[17] that OSHA set in motion the chain of events that ultimately brought the present controversy to this Court. The Infante Study found a five-fold

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characterizes as concluding that benzene "must be considered a carcinogen." OSHA Br. 11. Actually, the Academy concluded that benzene may be "relatively weak or no[t] leukemogenic" at all, particularly at low exposure levels, and could only conclude that it is a "suspect leukemogen." Exh. 2-4 at ii, iii.

[15] *See* Exhs. 93A., 93.G.1, 93.G.2 (service station exposure data). Gasoline contains, on the average, about 2% benzene. Pet. App. 69a.

[16] Arthur D. Little, Inc., *Economic Impact Statement for Benzene* 1-7 (May 1977) (Exh. 5). Arthur D. Little was OSHA's economic contractor for the Benzene Standard.

[17] Infante *et al., Leukemia Among Workers Exposed to Benzene* (April 28, 1977) (Exh. 40). Earlier drafts of the study, dated April 15 and 26, 1977, are contained in the record as Exhs. 2-7 & 2-51.

increase in leukemia deaths among workers exposed to benzene during the 1940's at two Pliofilm[18] plants in Akron and St. Mary's, Ohio.[19] Without even consulting the available exposure monitoring data, OSHA misinterpreted the Study as associating the excess incidence of leukemia with benzene exposures "generally below 25 ppm"[20] or even "significantly below . . . 10 ppm."[21]

Based on this misconception, OSHA, on April 29, 1977, issued an Emergency Temporary Standard ("ETS") for benzene under Section 6(c) of the Act. 29 U.S.C. § 655(c).[22] The ETS imposed a 1 ppm exposure limit (as well as numerous other requirements) without any indication that alternatives,

[18] Pliofilm was a type of plastic food-wrapping material manufactured until the 1960's. Exh. 115.B-6 at 5-6; Tr. 766.

[19] OSHA's lawyers suggest that the Infante Study may seriously understate the actual incidence of leukemia experienced by Pliofilm workers. OSHA Br. 15 n.17. However, Dr. Infante himself testified that none of the additional leukemia cases reported by Dr. Sakol were within the population of workers which he (Infante) studied. Tr. 769. If Infante had expanded his study to include these cases, the enlarged study population would also have included far more non-leukemia deaths. Nor would the fact that leukemia is not listed on a death certificate (even though it may be the real cause of death) lead to an understatement of the comparative mortality, since the mortality among the study population is compared to the mortality experience of the general population, which is also based on death certificates that would reflect a similar degree of underreporting. *See* Tr. 1401-02, 1446-47.

[20] Preamble to the Emergency Temporary Standard for Benzene, 42 Fed. Reg. 22516 (May 3, 1977) (Exh. 1).

[21] OSHA Opposition to Stay Pending Judicial Review of the ETS, API v. OSHA, No. 77-1973 (5th Cir., filed June 1, 1977). *See* API Post-Hearing Br. 24-25 (Exh. 217-33).

[22] The ETS was published in the Federal Register on May 3, 1977. 42 Fed. Reg. 22516 (Exh. 1).

either more or less stringent than 1 ppm, had ever been considered.[23]

The ETS never took effect. It was challenged by many of the respondents here and was stayed by the Courts of Appeals for the Fifth and District of Columbia Circuits.[24] In the meantime, pursuant to Section 6(c)(3) of the Act, 29 U.S.C. § 655(c)(3), OSHA proposed a permanent benzene standard, which was essentially identical to the ETS,[25] and held hearings on the proposal between July 19 and August 10, 1977.

At the hearings, OSHA's interpretation of the Infante Study was quickly shown to be seriously in error. Contrary to OSHA's initial view that the workers studied by Dr. Infante were exposed to less than 25 ppm benzene, the evidence and testimony established that they probably were exposed to average benzene concentrations of 100 ppm, with excursions (for as long as thirty minutes at a time) that

[23] In fact, OSHA never cited any basis for its original choice of 1 ppm. In issuing the ETS, OSHA claimed that the 1 ppm level was based on a feasibility investigation by Arthur D. Little, Inc. 42 Fed. Reg. at 22521. But this study really did nothing more than estimate the compliance costs for the emergency 1 ppm exposure standard *already selected by OSHA*. *See* Arthur D. Little, Inc., *Compliance Costs for Benzene Emergency Temporary Standard* 4 (May, 1977) (Exh. 5). ("The objective of this study was to assess the costs of compliance for the proposed emergency regulation").

[24] API, *et al.*, v. OSHA, *et al.*, No. 77-1973 (5th Cir., Orders dated May 19 and June 6, 1977); Industrial Union Dep't, AFL-CIO v. Bingham, 570 F.2d 965, 187 U.S. App. D.C. 56 (1977).

[25] Proposed Permanent Standard, 42 Fed. Reg. 27451, 27460-64 (May 27, 1977) (Exh. 4).

ranged as high as 1,000 ppm.[26] The authors of the Infante Study conceded these points,[27] and one of them testified that OSHA had gone "off the deep end" in interpreting the Study as demonstrating that "exposures generally below 25 ppm have already induced leukemia."[28]

Consequently, OSHA was ultimately forced to concede that the Infante Study did no more than "provide[] additional evidence supportive of earlier studies," and that these "positive studies," including the Infante Report, "involve[d] high exposure levels." Pet. App. 107a, 124a. When so interpreted, the Infante Study added nothing new to the evidence which OSHA and various scientific groups had previously found insufficient to justify changing the current 10 ppm standard.

2. The absence of excess leukemia from low-level benzene exposures

With OSHA's initial erroneous interpretation of the Infante Study refuted, the search for evidence linking low-level benzene exposures with the development of leukemia had to focus on other studies.

[26] The court below accepted "that exposure was probably around 100 ppm . . . [and occasionally] as high as several hundred parts per million." Pet. App. 8a n.13 (581 F.2d at 498 n.13). The voluminous record evidence on this issue is summarized in API Post-Hearing Br. 23-37 (Exh. 217-33); Post-Hearing Brief of the American Iron and Steel Institute ("AISI") 35-44 (Exh. 217-36).

[27] *E.g.*, Testimony of Dr. Infante and Ronald Young, Tr. 988-989, 995.

[28] Testimony of Ronald Young, Tr. 815-816. Dr. Infante and Edward J. Baier, Deputy Director of NIOSH, also rejected any such interpretation of the study. Tr. 1137-1140.

These studies, however, served only to confirm the absence of any discernible excess incidence of leukemia from benzene exposures below 100 ppm.

For example, it was shown that when benzene exposures were reduced below 100 ppm—*but not eliminated*—the excess incidence of leukemia found in the principal studies cited by OSHA (the reports of Drs. Infante, Aksoy and Vigliani) *ceased to occur.* Nowhere was this seen more clearly than in the workplaces studied by Dr. Infante. Studies by the University of North Carolina of persons who worked in the same two Pliofilm plants examined by Dr. Infante, but at a later time when benzene exposures probably averaged 35 ppm or less, failed to uncover any excess incidence of leukemia.[29] Precisely the same result occurred in the work environments studied by Drs. Aksoy and Vigliani.[30]

This evidence that low-level benzene exposures present no significant risk of leukemia was bolstered by a series of epidemiologic studies of hundreds of thousands of workers exposed to low concentrations

[29] D. Andjelkovic *et al.*, *Mortality Study of Rubber Workers with Special Reference to Work Exposure—Goodyear Akron Plants* 49, Tables B-5, 13 (July 1976) (Exh. 187. B-13). *See* API Post-Hearing Br. 56-57 (Exh. 217-33).

[30] As noted by the court below (Pet. App. 8a n.13 (581 F.2d at 498 n.13)), both Drs. Aksoy and Vigliani reported no increased incidence of leukemia in the worker populations they studied once the use of solvents with high benzene content was halted. Pet. App. 100a-101a, 102a. The record shows that these substitute solvents were toluene and gasoline, containing up to 15 percent benzene, and that these solvents were used at a time when the permissible level of occupational exposure was 20 ppm in both Italy and Turkey. *See* API Post-Hearing Br. 61-65 (Exh. 217-33).

of benzene. Thus, the Thorpe Study of 38,000 European refinery workers, the Tabershaw/Cooper Study of 21,000 American refinery workers, and Stallones' Study of the mortality experience of 42,000 Shell Oil Company workers, all failed to uncover any excess incidence of leukemia among workers exposed to low concentrations of benzene.[31] These results were consistent with the findings of a long-term mortality study of the steel industry, which showed that coke oven and by-product facilities workers, exposed over the years to low concentrations of benzene, had not experienced any excess incidence of leukemia.[32]

To be sure, these negative studies had their methodological imperfections—imperfections which, for the most part, were acknowledged by their authors.[33] But, contrary to OSHA's suggestion (OSHA Br. 18 & n.19), the record shows that these shortcomings almost certainly did not conceal a significant leukemia problem among the worker populations studied. For example, statistical evaluations of Thorpe's data indicated strongly that neither the problem of incomplete follow-up[34] nor the possible "dilution" of the results by inclusion of unexposed workers[35] affected the validity of Thorpe's

[31] *See* API Post-Hearing Br. 65-75 (Exh. 217-33).

[32] *See* AISI Post-Hearing Br. 59-60 (Exh. 217-36). Individual steel company reports confirmed the results of this industry-wide study. *Id.* 60-62.

[33] *See* API Post-Hearing Br. 65-75 (Exh. 217-33) (citing testimony).

[34] *See* Testimony of Dr. Steven H. Lamm, Tr. 2663.

[35] *See* Thorpe Study 378 (Exh. 2-34). In addition, Dr. Robert Snyder testified that "using the most powerful statistical tools

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conclusions. The National Academy of Sciences' appraisal of the Thorpe Study is essentially the same.[36]

In sum, the record contains evidence associating high-level benzene exposures of 100 ppm or more with an excess incidence of leukemia. But the evidence also indicates that benzene exposures of 10 ppm or less are unlikely to lead to any leukemia *at all—i.e.*, there is evidence of a threshold or "safe" exposure level well in excess of 10 ppm for the leukemogenic effects of benzene.[37] OSHA rejected this position, relying on a regulatory "policy assumption" that there is no safe level for exposure to any carcinogen. Pet. App. 181a-186a.[38] The court below, with some misgivings, upheld OSHA on this point. Pet. App. 18a (581 F.2d at 503). But whether or not the available evidence established the existence of a

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available and concentrating on the most highly exposed population of workers, it was not possible to detect a greater incidence of leukemia [in the Thorpe Study] than in the population at large." Exh. 156-2 at 17.

[36] NAS Report ii (Exh. 2-4): "In spite of the inherent shortcomings of Thorpe's study, it does seem to indicate that there is not an outstandingly high incidence of leukemia in the workers studied."

[37] The empirical data on this point were bolstered by extensive biochemical and theoretical evidence for the existence of a threshold level for the production of benzene-related leukemia. *See* API Post-Hearing Br. 85-91 (Exh. 217-33); AISI Post-Hearing Br. 51-57, 66-71 (Exh. 217-36).

[38] OSHA's lawyers attempt to leave the misleading impression that OSHA made its "no safe level" determination for benzene on a *factual* basis. OSHA Br. 17-19 & nn.19, 21. Actually, that determination reflects little more than an irrebuttable policy presumption which OSHA applies to all carcinogens. *See* Preamble to the ETS, 42 Fed. Reg. at 22517 (Exh. 1); OSHA's Proposed Cancer Policy, 42 Fed. Reg. at 54165-67. Indeed, OSHA stressed at the outset of the benzene hearings that it knows of no evidentiary showing which could ever overcome its "no safe level" policy presumption. Testimony of Grover Wrenn, Tr. 50-52.

threshold for benzene-related leukemia, it clearly confirmed the conclusion of the International Workshop that leukemia from benzene exposure below 10 ppm "would be a rare occurrence." *See* p. 9, *supra*.

3. The absence of any evidence showing that the standard would produce material or appreciable benefits

With even OSHA's medical witnesses unable to identify any association between low-level benzene concentrations and an excess incidence of leukemia,[39] one might have expected that OSHA would at least have utilized well-recognized extrapolation techniques to estimate the leukemia risk at levels of 10 ppm and below. But this OSHA refused to do, or even to attempt to do. OSHA provided no explanation for this refusal in its final Federal Register notice, and, at the hearings, all it could offer was the observation of Grover Wrenn, then OSHA's Deputy Director for Health Standards, that "there is no *definitive* dose-response relationship which would allow one to estimate quantitatively the degree of health protection afforded" by the standard. Tr. 131 (emphasis added).

Although the estimated cost of the proposed standard was substantial—one billion dollars on a discounted-present-value basis, and possibly much more[40]—OSHA never asked its economic contractor,

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[39] *See* Testimony of Grover Wrenn, Tr. 131; testimony of Dr. Muzaffer Aksoy, Tr. 187-89, testimony of Dr. Bernard Goldstein, Tr. 365.

[40] This $1 billion cost estimate for OSHA's proposed standard was derived from the cost estimates of OSHA's economic contractor, A.D. Little. A. 41. A.D. Little's estimates however, were challenged as significantly understated by as much as $4 billion. A. 127-28; Exh. 115.A-9 at 30-41.

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Arthur D. Little, Inc., to consider alternatives to a 1 ppm standard or to develop information concerning the health benefits that the standard might achieve. Accordingly, A.D. Little only parroted OSHA's claim about the absence of a "precise dose-response relationship" (Exh. 5 at 3-5), and was itself unable to "attach any significance to the reduction in benzene levels" mandated by the standard. Tr. 516-17.[41]

In light of the substantial resources at stake, as well as the absence of any demonstrated leukemia risk below 100 ppm, the President's Council on Wage and Price Stability ("President's Council") urged OSHA to evaluate the record evidence more closely to learn more about the potential health benefits, if any, of a 1 ppm standard. As the President's Council explained:

> Since OSHA is faced with a finite quantity of society's resources, or maximum costs that can be allocated to worker safety and health in any industry, OSHA should pay serious attention to the development of standards which will deliver the maximum increment of worker safety and/or health from every dollar spent on compliance.

A. 126. Even though the President's Council expressly recognized that "an accurate calculation"

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A.D. Little was never asked to provide a cost estimate for OSHA's final standard, which differed in certain respects from the standard originally proposed. The court below referred to the standard as having a "one-half billion dollar price tag" (Pet. App. 18a (581 F.2d at 503))—which it apparently derived, not on a discounted-present-value basis, but simply by adding the engineering and first-year operating costs estimated by OSHA in the Federal Register. *Id.* 17a (581 F.2d at 503), 133a-136a. If one assumes a 10% discount rate and applies it to OSHA's cost estimates, the total cost of the final standard (on a discounted-present-value basis) is approximately $810 million.

[41] *But see* n.42, *infra*.

might not be possible, it urged OSHA to develop benefit estimates for the 1 ppm proposal and possible alternative standards, using "[v]arying assumptions about the dose-response relationship" to obtain "a range of estimates" that would be of considerable "aid [to] OSHA in setting the final standard." A. 130.

This recommendation was echoed by Dr. Richard Zeckhauser of Harvard's School of Public Health, who testified that such a "range of estimates" is essential if OSHA is to achieve "the maximum level of health protection for whatever level of resource expenditure that we make." A. 130, 137.[42]

Whatever contrary implication may emerge from OSHA's Brief, neither the President's Council nor Dr. Zeckhauser ever suggested that OSHA must place a dollar value on human life. Rather, they simply urged that OSHA regulate as intelligently as possible, using "full information so that people in authority ... can see what trade off[s] they are making." A. 42. If a standard will only "buy minuscule protection for an extra-ordinarily high amount," then "we will find that we have achieved less for health and safety than we could have." A. 48, 137.

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[42] Significantly, OSHA's own economic contractor, A.D. Little, testified that it was capable of performing the type of "cost-effectiveness" analysis called for by the President's Council and Dr. Zeckhauser. *See* Pet. App. 19a (581 F.2d at 504); Testimony of Dr. Lawrence Partridge, Tr. 512, 515, 518. OSHA, however, never asked A.D. Little to perform such an analysis. *See* p. 17-18, *supra*.

In asking for "full information," both the President's Council and Dr. Zeckhauser acknowledged the absence of "precise" data associating the dose (or exposure) with the response (excess leukemia). *See e.g.*, A. 130, 144, 159. But neither viewed the absence of a "precise" dose-response relationship as an excuse for OSHA's failure to do a better job. Dr. Zeckhauser testified that other federal health and safety agencies often develop a "broad range" or even a "maximum estimate of the benefits," and that such estimates "would be of immense value" to OSHA in evaluating its proposal. A. 54, 144. For "it is quite possible in this case that knowing the maximum benefit might tell us what we shouldn't do. It might tell us that this present decision is wrong." A. 54. *See generally* A. 42-45, 54-55, 82, 130, 144, 159; API Post-Hearing Brief at 92-93 (Exh. 217-33).

As a demonstration of how such an "upper-bound" estimate might be made, Dr. Richard Wilson, head of Harvard's Energy and Environmental Policy Center, provided OSHA with an analysis that incorporated a series of conservative assumptions designed to overstate the actual risks encountered in exposure to benzene. His analysis showed that the leukemia risk from benzene exposure at 10 ppm is exceedingly small—indeed, it is comparable to the cancer risk associated with such everyday activities as air travel or eating or drinking normal amounts of commonly available foods and liquids. A. 79-80, 174. *See* p. 76, *infra*. Overall, Dr. Wilson estimated that by reducing benzene exposures to 1 ppm, OSHA could expect to prevent, at most, one case of leukemia (and one other assumed case of cancer) every six years. A. 81.

Dr. Wilson's demonstration was soon supported by the results of an analysis prepared by the Environmental Protection Agency ("EPA"), assessing the risk of leukemia to the entire American population presented by ambient benzene concentrations in the parts per billion range. A. 15-29. Because of its obvious relevance, OSHA submitted EPA's demonstration to the court below, which was relied on in its decision. *See* Pet. App. 19a n.23 (581 F.2d at 504 n.23). When EPA's results were converted from an environmental context (with a population basis of 215 million people) to an occupational context (of 30,000 workers exposed below 10 ppm), its conclusions were shown to be virtually identical to those reached by Dr. Wilson. A. 30-33. If anything, EPA's assessment suggested that Dr. Wilson had been unnecessarily conservative in several respects, and that a more realistic estimate was that OSHA's 1 ppm standard would prevent, at most, only one case of leukemia every 15 to 38 years. A. 33-34.

C. OSHA's Determination of "Appreciable Benefits" in Support of the Final Standard

Even though it was forced to concede that the Infante Study, like the earlier reports, showed no association between benzene exposures of less than 100 ppm and the development of leukemia, OSHA retained a 1 ppm limit in its final standard. Despite all the attention that had been given at the hearings to the question of what, if any, additional health benefits might be achieved by reducing the present standard from 10 to 1 ppm, OSHA brushed the issue aside, devoting barely one page out of its lengthy 50-

page Federal Register notice to a discussion of the question. 43 Fed. Reg. at 5940-41. Pet. App. 158a-163a.

OSHA's Brief attempts to leave the erroneous impression that the evidence summarized above was squarely addressed and rejected on the grounds that "the lack of data made it impossible to quantify the health risk at various levels of exposure," and that such an analysis was, in any event, barred by Section 6(b)(5) of the Act. OSHA Br. 23. But, in fact, nowhere in OSHA's Federal Register notice is there a logical or meaningful discussion of these two issues. Nor does OSHA address the record evidence in a coherent and rational manner. All OSHA's Federal Register notice does is to "determine" that the benefits of a reduction to 1 ppm "are likely to be appreciable," without citing any supporting evidence.

To be sure, OSHA's Federal Register notice does begin by citing Section 6(b)(5) of the Act, which it says directs the Secretary "to set standards which attain the 'highest degree of health and safety protection for the employee." Pet. App. 159a. Nowhere does OSHA contend, however, that an estimate of benefits is prohibited by Section 6(b)(5). To the contrary, it asserts that "a systematic evaluation" of benefits as well as costs *"is to be encouraged." Id.* (emphasis added).

Having provided this inconclusive interpretation of the Act, OSHA then purports to address the record evidence concerning health benefits. It first asserts that "a *precise* quantitative relationship" between dose and response "cannot be established" for benzene. Pet. App. 160a (emphasis added). OSHA makes no mention, however, of the experience of virtually every other federal health and safety agency (or of the uncontradicted evidence in this case), demonstrating that rough but educated estimates can be made, and that such estimates would be "of immense value" in enlightening OSHA's decision—even in the absence of "precise" dose-response data.

Nor does the Federal Register notice provide a rational explanation for OSHA's decision to reject outright the risk demonstrations for benzene discussed above. Rather, OSHA simply announces that it is "unwilling to rely" on Dr. Wilson's estimates, citing no record evidence except the Infante Study. OSHA nowhere explains why the Infante Study, which, along with other studies relied on by OSHA, formed the basis for Dr. Wilson's extrapolation, should lead to rejection of Wilson's results—particularly in light of the confirmatory EPA assessment which relied exclusively upon Dr. Infante's data. Pet. App. 161a.

Perhaps most astounding of all is OSHA's "determin[ation]" that the benefits of its 1 ppm standard "are likely to be appreciable." Pet. App. 160a, 162a. OSHA makes this "determination" even though it admittedly made no attempt to evaluate the benefits of a 1 ppm standard (or any other alternative level). Not surprisingly, OSHA cites no supporting evidence for its "determination," even though all OSHA's "determinations" are required by law to be supported by "substantial evidence."

OSHA ends its "benefits" discussion in the same self-contradictory manner as it began. On the one hand, OSHA announces that "it may not substitute cost-benefit criteria for the legislatively determined directive of protecting all exposed employees" but, on the other hand, it claims (again without record support) that "the substantial costs" of its standard "are justified in light of the hazards of exposure to benzene." Pet. App. 163a.

D. The Decision of the Court Below Reversing OSHA's "Appreciable Benefits" Determination

The court below vacated OSHA's benzene standard in its entirety, finding that "substantial evidence does not support OSHA's conclusion that [the] benefits [of its standard] are likely to be appreciable." Pet. App. 18a (581 F.2d at 503).[43] In reaching this conclusion, the court reviewed the evidence of an association between high-level (greater than 100 ppm) benzene exposures and an excess incidence of leukemia. Pet. App. 6a-9a (581 F.2d at 498-99). It also summarized the results of years of scientific research and practical experience that failed to document any actual cases of leukemia from exposures below 100 ppm, and expressly noted OSHA's failure "to point to any empirical evidence documenting a leukemia risk at 10 ppm"—the level of the present standard. *Id.* 18a (581 F.2d 503).

[43] Because the standard was vacated in its entirety, the court below was not required to reach respondents' separate challenge to the various provisions that are supposedly ancillary to a 1 ppm exposure limit. Pet. App. 22a, 33a (581 F.2d at 505, 510). Even if the decision below were reversed, the case would have to be remanded to the Fifth Circuit for consideration of these additional issues.

The essence of the court's holding is that OSHA must do more than it did in *this* case to show that its 1 ppm benzene standard is reasonable and not arbirary.[44] Although OSHA had estimated what its standard would cost, it had made no effort whatsoever to look at the degree of risk prevented (and hence the benefits achieved) by reducing benzene exposures to 1 ppm. OSHA's failure to consider this question was considered inexcusable, particularly in light of the record evidence before the agency and the court showing that the benefits of the standard were likely to be exceedingly small. Pet. App. 19a n. 23 (581 F.2d at 504 n.23). Consequently, the court ruled that OSHA could not justify the reasonableness of a 1 ppm standard unless it did more than simply assume that the benefits resulting from a reduction to 1 ppm would be appreciable. Pet. App. 19a (581 F.2d at 504).

In reaching its decision, the court construed the Act as requiring that evidence on risks, benefits and costs play a part in OSHA standard-setting. In addition to the substantial evidence test of Section 6(f), the court relied on Sections 2(b), 3(8) and 6(b)(5) of the Act. The court cited approvingly respondents' argument that Section 2(b) requires OSHA to "assure maximum benefit from the finite amount industry can expend on safety and health." Pet. App. 14a (581 F.2d at 501). And it viewed

[44] Basically, the court envisioned a two-step process. First, OSHA must identify the approximate degree of risk prevented (*i.e.*, the benefits produced) by its standard. Pet. App. 18a-21a (581 F.2d at 503-05). Only when this first step has been completed is it appropriate to consider whether the estimated benefits bear any "reasonable relationship" to the costs imposed by the standard. *Id.* In this case, OSHA never completed the

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Section 3(8)'s "reasonably necessary" requirement as a concise statement of Congress' intent that OSHA issue more reasonable and better-supported standards than it did in this case. Pet. App. 13a-16a (581 F.2d at 501-03).

The court found compelling reasons for reversal in the "pragmatic limitations" of Section 6(b)(5). *Compare* OSHA Br. 31-32 *with* Pet. App. 15a-16a (581 F.2d at 502). In the court's words, Section 6(b)(5) "requires standards to be feasible and . . . contains a number of pragmatic limitations in the form of specific kinds of information OSHA must consider in enacting standards." Pet. App. 15a-16a (581 F.2d at 502). The court concluded that these "pragmatic" requirements—together with the non-absolute approach to regulation reflected in Sections 2(b) and 3(8)—deprive OSHA of "the unbridled discretion to adopt standards designed to create absolutely risk-free workplaces regardless of cost." Pet. App. 15a (581 F.2d at 502).

Although the court construed the Act as requiring OSHA to consider the benefits of its actions as well as the costs, it cautioned that OSHA does not have to "conduct an elaborate cost-benefit analysis" in order to make the pragmatic judgment that the Act requires. Pet. App. 17a (581 F.2d 503). All the court required is that OSHA "regulate on the basis of knowledge rather than on the unknown," and that it "have some factual basis" for making "rough but educated estimates of the extent of benefits expected"—where, as here, such educated estimates are

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first step, *i.e.*, it failed "to provide an estimate of expected benefits from reducing the permissible exposure limit," thereby making it "impossible to assess the reasonableness of the relationship between expected costs and benefits." *Id.* 21a (581 F.2d at 504).

possible. Pet. App. 20a-21a (581 F.2d at 504).[45] Accordingly, affirmance of the decision below would not preclude OSHA from conducting further proceedings and adopting a revised benzene standard in accordance with the requirements of the Act.[46]

SUMMARY OF THE ARGUMENT

This case calls upon the Court to decide whether, in adopting occupational health standards, OSHA must: (i) attempt to identify the benefits (in the

[45] OSHA is also wrong when it says that the court considered such a "rough but educated" estimate to be "impossible." OSHA Br. 32. To the court, "impossibility" was only OSHA's "assertion," to be proved or disproved in any further proceeding that OSHA might choose to hold on benzene. Pet. App. 19a n.23 (581 F.2d at 504 n. 23). But it is hard to read the court as being anything but skeptical about OSHA's impossibility "assertion," since it noted that "preliminary assessments are now being made" (citing the EPA risk assessment), and that "OSHA's economic consultant testified that it could perform a cost-effectiveness analysis . . . which would have included some kind of risk quantification." *Id.* 19a n.23 (581 F.2d at 504 n.23). *See* pp. 17-21 & n. 42, *supra*.

Nor should OSHA read more into the expression "reasonable relationship" than the court did. Stripped to its essentials, the holding of the court required only that OSHA must consider evidence on both benefits and costs. Although the court referred to a "reasonable relationship" between the two, it gave no substantive content to that expression. What "reasonable relationship" meant to the court (other than OSHA's obligation to consider benefit and cost evidence and to explain how it exercised its discretion in light of such evidence) was never reached because the inadequate record before the court made it "impossible" to go further in this case. Pet. App. 21a (581 F.2d at 505).

[46] The court said as much when it noted that OSHA need not "wait until deaths occur . . . [before] it may validly promulgate a standard reducing the permissible exposure limit." *Id.* 20a (581 F.2d at 504). But whatever OSHA might be able to prove on a new record, the court held that "in *today's case* . . . Congress intended OSHA to regulate on the basis of more knowledge and fewer assumptions than *this record* reflects." *Id.* 21a (581 F.2d at 505) (emphasis added).

form of reduced health risks) that its standard is expected to achieve, and (ii) consider those benefits in light of the costs imposed by the standard. While OSHA concedes that this is a useful exercise that is performed under many health and safety statutes, it contends that the OSH Act is not an "ordinary statute." OSHA Br. 36. In OSHA's view, the OSH Act bars any consideration of these matters, with the sole exception that control costs may be taken into account if (and only if) the standard would drive entire industries or large numbers of employers out of business. Pet. App. 133a.

The OSH Act would have to be an extraordinary statute indeed if it condoned ignoring the kinds of evidence described above. But it is not such a statute. Unlike the Endangered Species Act of 1973, or the Delaney Clause of the Food, Drug, and Cosmetic Act, the OSH Act aims at relative rather than absolute protection. Throughout, its objectives and directives are stated in qualified rather than categorical language. And its legislative history confirms that Congress wanted OSHA to be pragmatic, setting safety and health standards that are reasonable and practical in light of all the evidence.

Other than repeating an out-of-context reading of a single sentence of the statute (OSHA Br. 36, 48, 55, 58), OSHA never attempts to explain Congress' use in the Act of such relative expressions as "feasible," "material," "adequate," "reasonably necessary" and "so far as possible." Yet it is hard to read these and other relative expressions as they are used in the Act without becoming convinced of Congress' pragmatic purpose. To be sure, Congress was concerned primarily with overall worker health and

safety. But that overriding goal can never be achieved unless OSHA seeks to allocate health and safety resources where they can be expected to do the most good. This pragmatic objective is antithetical to allocating enormous resources to prevent a *de minimis* health risk, as OSHA did here.

Congress realized that, in order to make informed and reasonable judgments about how workers can be best protected and how resources can be best allocated, OSHA would need to consider *all* of the available evidence. The Act spells this out in so many words in Section 6(b)(5). Specifically, standards must be based on "the best available evidence," including "research, demonstrations, experiments, and such other information as may be appropriate." Of special importance in this case is the further requirement that OSHA consider "the latest available scientific data in the field" and "experience gained under this and other health and safety laws."

The decision below requires no more (and in many instances, a good deal less) than what other federal health and safety agencies are already doing. These agencies, including the Environmental Protection Agency, the Food and Drug Administration, the Nuclear Regulatory Commission and the National Highway Traffic Safety Administration, all make what the court below called "rough but educated estimates" of the benefits of their respective health or safety standards. This approach has been endorsed by the President's Science Advisors and was recommended by the President's Council on Wage and Price Stability in this very case. Therefore, OSHA had a heavy burden to show, at a minimum, why it

could not do what is routinely being done by a host of federal health and safety agencies under "other health and safety laws."

OSHA cannot dispense with this and other requirements of the Act simply by defining "feasible" in such a way that the benefits of its standards become irrelevant and the control costs become a matter to be considered only if the standard in question threatens an industry's financial survival. This extreme stance defies not only common sense but also the legislative history. For what Congress wanted, as revealed by two separate amendments on the subject, was for OSHA to set reasonable and practical standards directed at "material" health hazards. As the evidence shows, that is not what OSHA did here.

In short, there are compelling reasons why the decision below should be affirmed. The court below was asked to uphold an enormously costly standard based upon nothing more than a scanty Federal Register notice that waffles back and forth between a poorly-articulated interpretation of the Act and a completely unsupported "appreciable" benefits "determination." This is precisely the type of arbitrary action that Congress intended to prevent when it subjected OSHA standards to the "substantial evidence" standard of review. If OSHA can rely upon a completely unsupported assumption to proclaim that the benefits of its standard "are likely to be appreciable" when the uncontradicted evidence shows the contrary to be true, then much of the Act, including the "substantial evidence" test, will have been drained of its intended meaning.

ARGUMENT

I. THE OSH ACT IS A PRAGMATIC STATUTE REQUIRING THAT OSHA USE THE "BEST AVAILABLE EVIDENCE," INCLUDING EVIDENCE ON RISKS, BENEFITS AND COSTS, TO SET "FEASIBLE" STANDARDS THAT ADDRESS "MATERIAL" WORKPLACE HAZARDS.

Stripped to its essentials, OSHA's position here reduces to the following: Once it determines that a substance is a carcinogen,[47] it *must* (subject to only one limitation) require that workplace exposure to the substance be eliminated *entirely*, to the extent that this can be accomplished by the use of existing technology or by technology that industry may develop in the future. The only limitation that OSHA would recognize is that its standard must not be so extraordinarily expensive that it would "drive entire industries or large numbers of employers out of business." Pet. App. 133a.[48]

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[47] Actually, OSHA takes the same position with respect to any toxic substance or harmful physical agent—carcinogenic or not—for which it believes no entirely safe level of exposure has been established. *See, e.g.*, Cotton Dust Standard, 43 Fed. Reg. 27350 (June 23, 1978); Lead Standard, 43 Fed. Reg. 52952 (November 14, 1978).

[48] *See, e.g.*, Cotton Dust Standard, 43 Fed. Reg. 27350, 27378 (June 23, 1978) ("[A]lthough some marginal employers may shut down, . . . the industry as a whole will not be threatened," so that "the productive capacity of the surviving firms . . . will be able to meet the demands for production of cotton products."); Lead Standard, 43 Fed. Reg. 52952, 52981-52983 (November 14, 1978) (While "some firms may choose to exit the market," the standard "assures economic viability" of, and will "not result in undue economic hardship on" the industries involved). *See also* text accompanying n.83 at *p. 60, infra.*

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According to OSHA, it is irrelevant that the present standard is already highly protective, that the risk (if any) from current exposures is exceedingly small, and that a further reduction to 1 ppm would produce only a minute reduction in an already small risk. Nor does OSHA acknowledge that the resources committed to controlling such small risks may be lost for other, more productive, health protection purposes. In short, OSHA deems benefits to be completely irrelevant and costs to be relevant only in the case of a possible industry shutdown. OSHA Br. 23, 48.

Common sense alone suggests that OSHA's interpretation goes too far. Surely, Congress did not intend industry, and ultimately the public, to expend vast sums at OSHA's command to eliminate even the most minuscule risk presented by a single substance so long as the industry could bear the cost and still survive. Nothing could frustrate the purpose of the OSH Act more completely than to have a grave or extraordinarily dangerous hazard go unregulated because the affected industry had already been driven to the limits of survival by the costs of controlling a far less serious risk addressed in a previous regulation. Yet this is the logical outgrowth of OSHA's

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OSHA's Brief takes the same position, *i.e.*, that the Act "leaves no room," and indeed "prohibits" taking benefits (and costs as related to benefits) into account in setting health standards. OSHA Br. 36, 38, 41, 48, 55, 32 n.33.

position, which takes account of costs only at the point of business collapse and which ignores benefits entirely.

Fortunately, there is a middle-ground where both costs and benefits are relevant and play a role in standard-setting. The Court need look no further than the Act and its legislative history to find this middle-ground. Indeed, once the focus expands from the selected portion of a single sentence of Section 6(b)(5)—upon which OSHA's case turns almost exclusively—it becomes clear that the Act as a whole requires consideration of risk, benefit and cost evidence in standard-setting.

As we show in Subpart A below, the starting point is the Act's overall purpose, Section 2(b), which expresses Congress' intent to provide—not the total elimination of individual hazards—but rather the most adequate protection against *all* health and safety hazards "so far as possible." This relative rather than absolute command is amplified in the definition of "occupational safety and health standard" (Section 3(8)), and is carried forward in the Act's standard-setting provisions (Section 6(b)).

In Subpart B, we focus specifically on the first sentence of Section 6(b)(5). As shown by the legislative history, the "feasibility" requirement there means that OSHA must demonstrate the "reasonableness" and "practicality" of its standards, taking account of all relevant considerations including risks, benefits, and costs. The requirement that OSHA consider evidence on risks and benefits is further underscored by the term "*material* impairment" which Congress substituted for an earlier version

("*any* impairment") in order to signify its intent that OSHA strive to eliminate "material" rather than inconsequential risks to workers.

Subpart C discusses the second and third sentences of Section 6(b)(5) and the "substantial evidence" review test of Section 6(f). Rather than permitting OSHA to rely on views, arguments and assumptions, the second and third sentences of Section 6(b)(5) require OSHA to develop standards on the basis of the "best available evidence"—including "research, demonstrations, experiments," "the latest available scientific data in the field," and "experience gained under this and other health and safety laws." Together with the "substantial evidence" test of Section 6(f), these provisions define the evidentiary context within which OSHA must consider all relevant information, including that relating to risks, benefits and costs.

In Subpart D, we show that OSHA's inconsistent and poorly-articulated interpretation of the Act is entitled to no deference by the Court. On the contrary, if any interpretation is entitled to weight, it is that of the Occupational Safety and Health Review Commission, an independent adjudicatory tribunal established by Congress as a check on potential abuse by the Labor Department. The Review Commission has consistently rejected OSHA's extreme position and adopted a construction consistent with the decision below.

Finally, Subpart E examines the role the courts have given to consideration of risks, benefits and costs under similar safety and health legislation. In general, except where such consideration is clearly

and unequivocally precluded, the courts have interpreted terms such as those in the OSH Act to allow consideration of risks, benefits and costs.

A. The OSH Act Consistently Speaks in Terms of Relative Rather Than Absolute Protection, Thereby Necessitating Consideration of Risk, Benefit and Cost Evidence.

OSHA's case here rests almost exclusively on an out-of-context reading of the first sentence of Section 6(b)(5) as providing that health standards "shall . . . assure[ ] . . . that no employee will suffer . . . impairment of health." 29 U.S.C. § 655(b)(5). It is from these words that OSHA derives its interpretation that risks and benefits are irrelevant, and that costs are relevant only if the standard in question would "drive entire industries or large numbers of employers out of business." Any fair reading of the Act as a coherent whole refutes this absolutist interpretation.

The starting point for interpreting the Act is the statement of general purpose found in Section 2(b). That purpose is "to assure *so far as possible* every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources." 29 U.S.C. § 651(b) (emphasis added). In order to achieve this objective, OSHA must conscientiously consider the need to expend society's limited health resources wisely.

This relative objective of assuring overall protection "so far as possible" contrasts markedly with the far more absolute commands of other statutes, such as the controversial Delaney Clause of the Federal Food,

Drug, and Cosmetic Act.[49] Another example is the Endangered Species Act of 1973, recently construed by this Court in *Tennessee Valley Authority v. Hill*, 437 U.S. 153 (1978). In *TVA*, the Court interpreted the Endangered Species Act as barring the completion of the Tellico Dam on the Tennessee River because, in the words of the statute, construction of the dam would "*jeopardize* the continued existence" of an "*endangered species*" (the snail darter) or "*result* in the destruction or modification of habitat of such species." 437 U.S. at 160, 173 (emphasis in original).

The Court reached this result reluctantly, only after noting that Congress had carefully omitted language from Section 7 of the 1966 Act and in Section 2(b) of an Administration bill which would have limited the obligation of federal agencies to preserving "endangered species only '*insofar as is practicable and consistent with the*[*ir*] *primary purposes.*' " *Id.* 175, 181 (emphasis in original). Characterizing it as "very significant" that "the final version of the 1973 Act carefully omitted all of the reservations described above," the Court proceeded to hold that neither it nor the Interior Department was authorized to weigh "the loss of millions of unrecoverable dollars" against "the loss of the snail darter." *Id.* 182, 187.

The OSH Act, beginning with the statement of purpose, imposes no similar prohibition against a

[49] *See* 21 U.S.C. § 348(c)(3)(A). The Delaney Clause is a classic example of a statute providing absolute health protection. In contrast to the relative terms used throughout the OSH Act, the Delaney Clause provides simply and unequivocally that "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal." *See* pp. 38, 66, *infra*.

pragmatic and cost-effective allocation of society's resources. On the contrary, unless OSHA attempts to determine, at least roughly, what benefits each of its standards is likely to achieve, it will inevitably squander finite health protection resources on insignificant risks and frustrate the Act's overriding purpose of providing overall "safe and healthful working conditions" "so far as possible."

The relative rather than absolute protection intended by Congress is seen throughout the OSH Act. Section 2(b)(3) "authoriz[es] the Secretary of Labor to set mandatory occupational safety and health standards" which are, in turn, defined by Section 3(8) as "conditions . . . *reasonably necessary or appropriate* to provide *safe or healthful employment* and places of employment." 29 U.S.C. §§ 651(b)(3), 652(8) (emphasis added). When construed most reasonably, both the object of such standards ("safe or healthful employment") and the means of achieving it ("reasonably necessary" conditions) are seen to be relative in nature.

Long before the decision below, commentators interpreted Section 3(8) as a qualified rather than absolute definition. According to Professor Currie, Section 3(8) "does not simply require whatever is 'necessary' to achieve the requisite level of safety, it requires what is 'reasonably necessary or appropriate.' "[50] And "[w]hat is 'appropriate' may be what is desirable in light of feasibility or cost; what is 'reasonably necessary' may be what is both necessary and reasonable."[51]

[50] David P. Currie, "OSHA," 1976 Am. Bar Foundation Research J. 1107, 1134 (1976).

[51] *Id.*

Similarly, the words "safe or healthful," as Professor Currie points out, allow "room for some play."[52] Like the concept of a "safe" drug under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*, the expression "safe or healthful" should be interpreted as seeking something less than perfection. As Judge Leventhal explained in *Hess & Clark, Division of Rhodia, Inc. v. FDA*, 495 F.2d 975, 993-94, 161 U.S. App. D.C. 395, 413-14 (1974), resolution of the issue of safety "inevitably means calculating whether the benefits which the drug produces outweigh the costs of its restricted use." *See also United States v. Rutherford*, 47 U.S.L.W. 4724, 4727 (June 19, 1979).

Like Sections 2(b) and 3(8), the standard-setting terms of Section 6 are qualified and relative.[53] Under the first sentence of Section 6(b)(5), individual health standards are to provide—not absolute protection—but instead only the "most adequate[ ]" protection against the health hazard to which the standard is directed. The requirements that protection be provided only "to the extent feasible" and

[52] *Id.*

[53] As one would expect, the objective of all three sections is the same. The first substantive criterion for a permanent standard issued under Section 6(b) is that it be designed "to serve the objectives of this chapter" (29 U.S.C. § 655(b)(1)) —*i.e.*, to provide protection against all occupational hazards "so far as possible." Likewise, whenever any permanent health or safety standard "differs substantially from an existing national consensus standard," OSHA must show that the permanent standard "will better effectuate the purposes of this chapter . . . ." 29 U.S.C. § 655(b)(8).

only against "material impairment" provide further pragmatic limitations, acknowledging the inevitable fact that there are some risks that it will not be "feasible" to eliminate, and others that must be disregarded as not "material," if workers are to receive the most adequate overall protection against all workplace hazards.

The second and third sentences of Section 6(b)(5), which apply to both health and safety standards,[54] contain further pragmatic limitations. By providing that standards be based upon "research, demonstrations [and] experiments," the second sentence amplifies the requirement that OSHA base its standards on "the best available evidence." Moreover, contrary to OSHA's implication (OSHA Br. 48), "the highest degree of health and safety protection for the employee" is but one of the "considerations" listed in the third sentence of Section 6(b)(5). Others include the "latest scientific data in the field," the "feasibility of the standards" and "experience gained under this and other health and safety laws."

Although OSHA is silent on the meaning of most of the expressions discussed above, its position appears to be that whatever Congress may have meant by relative expressions such as "so far as possible," "reasonably necessary," "adequately," "to the extent

[54] Under the Act, OSHA is authorized to set four types of occupational safety and health standards. The first two types, interim standards and emergency temporary standards, are governed by Sections 6(a) and 6(c), respectively. 29 U.S.C. § 655(a), (c). The remaining two types of occupational safety and health standards—permanent safety standards and permanent health standards, are governed by the provisions of Section 6(b), 29 U.S.C. § 655(b). *See* p. 50 n.70, *infra*.

feasible" and "material" is overridden by the use of supposedly absolute terms such as "no employee" in the first sentence of Section 6(b)(5). *E.g.*, OSHA Br. 36, 41-42, 48, 53. Yet, similar language elsewhere in the Act has been construed in a practical, rather than absolute manner by the courts.

For example, OSHA points to the so-called "general duty clause" of Section 5(a)(1) of the Act as an example of the Act's preference for absolute protection without regard to costs. OSHA Br. 52. That provision requires an employer to "furnish to *each* of his employees employment and a place of employment which are *free* from recognized hazards that are causing or are likely to cause death or serious physical harm . . . ." 29 U.S.C. § 654(a)(1) (emphasis added). The courts, however, have held that "Congress quite clearly did not intend the general duty clause to impose strict liability" even though the term "free" is concededly "unqualified and absolute." *National Realty and Construction Co. v. OSHRC*, 489 F.2d 1257, 1265-66, 160 U.S. App. D.C. 133, 141-42 (1973). Rather, the clause requires only "*demonstrably feasible*" measures that "*materially reduce*[ ]" the likelihood of harm. 489 F.2d at 1267, 160 U.S. App. D.C. at 143 (emphasis added).[55]

[55] *Accord*, Champlin Petroleum v. OSHRC, 593 F.2d 637, 640 (5th Cir. 1979) (Violation of the general duty clause had not been established because of "the lack of evidentiary support for the underlying assumptions" that the measures the employer failed to use "would materially reduce the hazard" involved.); Titanium Metals Corp. of America v. Usery, 579 F.2d 536 (9th Cir. 1978) (Because the OSH Act "was never designed, nor could it have been, to eliminate all occupational accidents," OSHA must demonstrate the "feasibility and likely utility" of protective measures in order to satisfy the general duty clause.).

In short, just as the expression "free" in the general duty clause should not be interpreted as "unqualified and absolute," so too the few words that OSHA relies upon must be tempered by Congress' use of relative expressions elsewhere in the first sentence of Section 6(b)(5) and throughout the Act. Acceptance of OSHA's construction would ignore these relative expressions and turn the OSH Act into an absolutist statute practically indistinguishable from the Endangered Species Act or the Delaney Clause of the Food, Drug, and Cosmetic Act. Congress clearly did not intend such a result.

B. Section 6(b)(5)'s Requirements That Health Standards Must Be "Feasible" and Must Address "Material" Health Hazards Necessarily Contemplate Consideration of Evidence on Risks, Benefits and Costs.

The key to OSHA's case, as previously noted, is the first sentence of Section 6(b)(5), which, OSHA says, "requires the Secretary to achieve the lowest possible risk" short of an industry shutdown. OSHA Br. 37.[56] In support of this position, OSHA claims that Congress "struck" a "compromise" that distinguished between health and safety hazards and applied "far

[56] OSHA bases this position not only upon what it views as the supposedly absolute language of the sentence discussed above, but also upon the word "feasible," which OSHA defines in strict dictionary terms as "capable of being achieved" or "done" with no further qualifications. OSHA Br. 38, 56. But the very definitions OSHA cites include pragmatic equivalents such as "practicable," "suitable" and "reasonable"—words far more liberal than OSHA's cramped interpretation of "feasibility" as any controls which can be implemented short of an industry shutdown. *See* I *Compact Oxford English Dictionary* 973 (1971); *Webster's Third New International Dictionary* 831 (1971).

more strict controls" to the former than the latter. *Id.* 37, 58-59. As we will show, OSHA's interpretation of the first sentence of Section 6(b)(5) collapses upon review of the legislative history.

1. **Addition of the words "feasible" and "material" was intended to assure that OSHA would adopt "reasonable" and "practical" health standards that do not squander vast resources on speculative or insignificant risks.**

From the outset of the legislative debate that produced the OSH Act,[57] Senator Javits was the key proponent of "feasible" standards. As the author of the original Administration bill (S. 2788), and the ranking minority member of the Senate Labor and Public Welfare Committee which considered the legislation, Senator Javits wanted standards to be "feasible" in the sense of being "reasonable" and "practical" as well as technologically achievable.

Senator Javits' original bill would have required an independent National Occupational Safety and Health Board[58] to submit any proposals for permanent standards "to the appropriate national standards-producing organization" for a report —which Senator Javits described as "a report on the

[57] Senator Javits described congressional consideration of the legislation as "the most bitter labor-management fight in years"—a fight which at times was "so bitter as to jeopardize the prospects for enactment of this bill during this session of Congress." Leg. Hist. 193, 194. Only after a series of compromises, summarized chronologically in Addendum B to this Brief, did the legislation pass both Houses.

[58] Consistent with the Administration approach, S.2778 vested standard-setting authority in an independent board, rather than in the Labor Department. S.2788 § 4(a), Leg. Hist. 36-37; Add. B 3b-4b, 8b-9b, *infra*.

feasibility of the proposed standards."[59] "Feasibility" for the purpose of such standard-setting was defined as including—"the *technical feasibility, reasonableness* and *practicality* of such standard."[60] This "feasibility report" was to be considered by the Board (along with other record evidence) in formulating its standards.[61]

The Senate Committee refused to go along with Senator Javits' proposal that occupational safety and health standards be set by an independent board, but agreed that "standards promulgated under Section 6(b) shall represent feasible requirements." Leg. Hist. 147. Accordingly, the term "feasibly" was added to Section 6(b)(5) by the Committee, thereby satisfying Senator Javits' concern that standards be reasonable and practical rather than "requir[ing] absolute health and safety protection in all cases . . . ." Leg. Hist. 197.[62]

[59] 115 Cong. Rec. 22517 (August 6, 1969).

[60] S.2788 § 4(c), Leg. Hist. 38-39 (emphasis added).

[61] *Id.* § 4(c)(2), (3), Leg. Hist. 39-40.

[62] *See* Add. B 8b-9b, *infra*. Without any citation to the OSH Act's legislative history on what "feasibility" was supposed to mean, OSHA argues that, in other statutes, Congress has distinguished between a feasibility requirement and a requirement that a cost-benefit analysis be performed. OSHA Br. 56 n.49. As previously discussed, however, the court below did not require a cost-benefit analysis in the sense OSHA uses that term. *See* pp. 2-5, 24-27, *supra*. Instead, OSHA need only take into account evidence on risks, benefits and costs, including "a rough but educated estimate" of benefits such as EPA and Dr. Wilson provided, or OSHA's economic contractor was capable of performing in this case. Pet. App. 19a n.23 (581 F.2d at 504 n.23). Because the court below did not go so far, there is no need to consider whether what OSHA says about these other statutes is correct.

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Even after the Senate Committee's inclusion of Senator Javits' "feasibility" amendment, many Senators were not satisfied. In pertinent part, the first sentence of Section 6(b)(5) then provided that "[t]he Secretary . . . shall set the standard which most adequately and *feasibly assures* . . . that no employee will suffer *any* impairment of health or functional capacity." Leg. Hist. 242 (emphasis added). This formulation was critized as "inherently confusing and unrealistic." Leg. Hist. 367.

First, the apparent prohibition against "any" impairment of health and "any" diminution of life expectancy was viewed as wholly impractical, since some risk was thought to be inherent in all employment. As Senator Dominick observed, "[n]o job can be rendered perfectly safe, and no employee can be

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One statute OSHA did not cite, the Federal Mine Safety and Health Act ("Mines Act"), 30 U.S.C.A. §§ 801 *et seq.* (Supp. 1979), helps to illustrate some of the differences between what the court below required and a cost-benefit analysis. The purpose of the Mines Act was to strengthen the Federal Coal Mine Health and Safety Act of 1970, which, in turn, was already far more stringent than the OSH Act. For example, the Coal Act required standards to assure "*to the greatest extent possible*" that no miner would suffer "*any disability*" (30 U.S.C. § 841(b) (1971) (emphasis added)) and contemplated that mines would be made "*as safe as present technology will permit.*" H. REP. NO. 91-563, 91st Cong., 1st Sess. 22, *reprinted in* [1969] U.S. Code Cong. & Ad. News 2524 (emphasis added).

To make the Coal Act even more stringent, the Mines Act deliberately dropped the expression "to the extent feasible" in the provision analogous to the first sentence of Section 6(b)(5) and adopted the more lenient "arbitrary and capricious" review standard. *See* 30 U.S.C.A. §§ 811(a)(6)(A), 811(d) (Supp. 1979); S. REP. NO. 95-312, 95th Cong., 1st Sess. 22, (1977). These changes were the result of Congress' concern about the "appallingly" and "unconscionably high" rate of injury and death among miners—"more than four times as great as the average for all manufacturing industries." S. REP. NO. 95-181, 95th Cong., 1st Sess. 7 (1977); H.R. REP. NO. 95-312, 95th Cong., 1st Sess. 3 (1977); 115 Cong. Rec. 2657 (daily ed., June 21, 1977).

rendered perfectly secure from injury," so that "[i]t is unrealistic to attempt, as this section apparently does, to establish a utopia free from hazards." Leg. Hist. 480.

Senator Saxbe pointed to the inevitable trade-off between employment and health, since "any type of exposure is going to affect" functional capacity and life expectancy. Leg. Hist. 338. Senator Dominick, citing examples of a bus or street car driver constantly exposed to risks of air pollution and traffic accidents (Leg. Hist. 423, 481), sought to eliminate any suggestion that health standards "must assure that there will not be any risk at all." Leg. Hist. 481. As Senator Dominick observed, "there is no way a criteria [sic] can be established so that an employee would not be faced with some risks for the period of his working life." *Id.* 481-82.[63]

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Reflecting the fact that feasibility was to play "a substantially less significant role" under the Mines Act (S. REP. NO. 181, 95th Cong., 1st Sess. 21 (1977)), the Senate voted down two proposed amendments which would have required an elaborate cost-benefit analysis before promulgating mine health or safety standards. *See* 123 Cong. Rec. S10218-S10224 (daily ed., June 20, 1977) and S10289-S10290(daily ed., June 21, 1977). But the legislative history shows that the fact that elaborate cost-benefit analyses do not have to be performed under the Mines Act does not relieve the Secretary of his obligation to consider risk, benefit and cost evidence. Specifically, the term "feasibility" (as it appears in the counterpart of the third sentence of Section 6(b)(5)) means "that the Secretary is required to indicate what his best estimate of the costs will be and of the benefits to workers." 123 Cong. Rec. S10290 (daily ed., June 21, 1977) (remarks of Senator Javits).

[63] Unless this and related problems were corrected by a more "balanced" bill, Senator Saxbe predicted health standards might amount to "harassing measures that would, in effect, limit production in areas that are not necessarily going to

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A second, closely-related concern was that the purpose of Senator Javits' "feasibility" amendment had not been given full effect in the Committee's bill. As Senator Dominick explained, the first sentence of Section 6(b)(5)

> could be read to require the Secretary to ban all occupations in which there remains *some* risk of injury, impaired health, or [diminished] life expectancy .... In addition, in many cases, the standard which most 'adequately' and 'feasibly' assures the elimination of the danger would be the prohibition of the occupation itself.

Leg. Hist. 367 (emphasis in original).

Neither Senator Williams, the floor leader of the Committee bill, nor any other Senator, expressed disagreement with these criticisms.[64] Senator Dominick initially proposed to drop the first sentence of Section 6(b)(5) altogether, but he soon laid aside an amendment to that effect in light of "modifications" that he was discussing with Senators Williams and Javits. Leg. Hist. 482. These "modifications," amending the first sentence of Section 6(b)(5) to its present form, easily passed the full Senate.

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increase safety." Leg. Hist. 320-21. If substantial resources had to be directed to eliminating such immaterial risks, the result, Saxbe feared, would not be "to make the plant safer ... but rather to make the business less competitive ...." *Id.* 321.

[64] The claim in OSHA's brief that supporters of the Senate Committee bill "embraced" these criticisms "as a description of their purpose" (OSHA Br. 37) is simply incorrect. Significantly, OSHA does not cite a single reference to the legislative history to prove its point.

In sum, addition of the word "feasible" to Section 6(b)(5) in the Javits and Dominick amendments was designed, in Senator Dominick's words, to assure that the Secretary would take only "such steps as are *feasible* and *practical*" to protect the health of employees. Leg. Hist. 502 (emphasis added). *See* Add. B 8b-9b, 13b-17b, *infra*. Likewise, the substitution of the term "*material* impairment" for the term "*any* impairment" was intended to prevent OSHA from regulating inconsequential health risks.[65] Taken together, the "feasibility" and "materiality" requirements of Section 6(b)(5) were intended to insure that OSHA would not waste vast resources in preventing immaterial risks through standards that are unreasonable and impractical.

2. Neither the Act nor its legislative history supports OSHA's portrayal of Senator Dominick's amendment as a "compromise" placing "more stringent controls" on health than on safety hazards.

Rather than address the real reasons for Senator Dominick's floor amendment,[66] OSHA would portray his changes as a "compromise," demonstrating that

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[65] While it is plausible, as a purely linguistic matter, to interpret this change as applying to the type of impairment involved, the legislative history shows that it was also intended to apply to the materiality of the risk. Add. B. 13b-18b, *infra*.

[66] None of the legislative history discussed above is anywhere mentioned by OSHA. Its Addendum is even less candid, claiming erroneously that "the only other modification" (apart from the specific reference to "toxic substances and harmful physical agents") was to shift, without explanation, from "most adequately and feasibly assures" to "most adequately assures, to the extent feasible." OSHA Br. 7a n.2. OSHA never discusses the important statutory change from "any" to "material" impairment, nor Senator Dominick's explanation for why the "feasibility" provision needed to be changed. Leg. Hist. 367.

"Congress wanted toxic substances placed under controls far more strict than those applicable" to safety hazards. OSHA Br. 37, 58. This claim that Congress cared more about lives lost to disease than to accident is contrary not only to common sense[67] but also to the language of the Act and the legislative history.

The Act itself (Section 2(b)(6)) does no more than "recogni[ze] . . . the fact that occupational health standards present problems often *different* from those involved in occupational safety." 29 U.S.C. § 651(b)(6) (emphasis added).[68] Nowhere does it say that health standards are to be more stringent.

The legislative history confirms the congressional recognition that health (as opposed to safety) hazards present special problems of identification and correction that warrant additional legislative guidance.[69] But this additional guidance for identifying and treating health hazards did not include a directive for more stringent regulation. Nor was any "compromise" of safety intended.

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[67] Significantly, both the House and Senate Reports stressed that 14,500 workers were killed, and 2.2 million disabled annually, mostly as the result of industrial *accidents*. Leg. Hist. 142 (Senate Report); Leg. Hist. 844 (House Report).

[68] According to Section 2(b)(6), these "different" problems include the difficulty of "establishing causal connections" between occupational exposures and disease either because of some delay in the onset of the disease (latency), or because cumulative exposures are needed before harm occurs. *See* Section 2(b)(6), 29 U.S.C. § 651(b)(6); Add. B 1b-2b, *infra*.

[69] The House Committee on Education and Labor, for example, observed that in contrast to safety hazards, which are "often immediately apparent," "[d]iseases resulting from occupational health hazards may not become known until years of continuous exposure have elapsed." Leg. Hist. 853-54. *See* Add. B 5b-6b, 15b-17b, *infra*.

In fact, the provision that became the first sentence of Section 6(b)(5) originated in the House Committee well before the Senate evolved the present text of Section 6(b)(5). Add. B 5b-6b, *infra*. As explained by the House Report, such a provision was necessary because "the committee feels it is vital that when the Secretary sets an occupational *health* standard he do so on the basis of the best available professional evidence," including evidence pertaining to the different problems presented by "regular exposure" to chemicals "for the period of the [employee's] working life." Leg. Hist. 848 (emphasis added). In short, the first sentence of Section 6(b)(5) was limited to "health standards" well in advance of the Dominick amendment adding the word "material" and clarifying the "feasibility" requirement. *See* Add. B 15b-17b, *infra*.

To be sure, only the legislative history in the House, not the statutory text, expressly restricted the first sentence of Section 6(b)(5) to health hazards. As Senator Dominick explained, however, this lack of specific reference to "toxic substances and harmful physical agents" was one of the deficiencies his amendment was intended to cure:

> What we were trying to do in the bill—unfortunately, *we did not have the proper wording or the proper drafting*—was to say that when we are dealing with *toxic agents or physical agents*, we ought to take such steps as are feasible and practical to provide an atmosphere within which a person's health and safety would not be affected.

Leg. Hist. 502 (emphases added).

Besides being contrary to Senator Dominick's explanation of his amendment as simply a drafting clarification, OSHA's claim that health standards are to be more stringent is fundamentally at odds with the text of Section 6(b)(5) itself. Thus, OSHA wrongly claims that "[s]tandards for hazards other than toxic substances and harmful physical agents are governed by other [unidentified] sections that lack the 'feasibility' phrase." OSHA Br. 58. But the plain wording of the Act makes the second and third sentences of Section 6(b)(5) applicable to *both* safety and health standards, and the third sentence specifically requires OSHA to consider the "feasibility" of standards.[70]

In short, "feasibility" is, as one would expect, a consideration that applies to all OSHA standards, whether addressed to illness resulting from exposure to toxic substances or to accidents caused by unsafe

[70] Unlike the first sentence of Section 6(b)(5), which applies only to "standards dealing with *toxic materials or harmful physical agents* under this subsection," the second and third sentences apply broadly to all "standards *under this subsection*"—*i.e.*, subsection (b) of Section 6, which prescribes how OSHA is to "promulgate . . . any occupational *safety or health* standard." 29 U.S.C. § 655(b) (emphasis added). This reading is confirmed not only by the third sentence (which refers to "health and *safety* protection"), but also by the legislative history. *See* Add. B 17b n.18, *infra*. If Congress had intended Section 6(b)(5) in its entirety to apply only to health standards, it would have used the term "paragraph" rather than "subsection," as other provisions of the Act show. *Compare* Sections 6(b)(6)(B) and 6(c)(3) (referring to actions taken "under this paragraph" and "in paragraph (2) of this subsection").

working conditions.[71] For each type of standard, the question that should properly be asked is whether the limits and conditions that OSHA proposes are "reasonable" and "practical" and provide real benefits to workers—not whether the affected industry can bear the costs and still survive. When the regulatory issue is framed in this manner, the relevance of evidence on risks, benefits and costs (such as the EPA and Wilson estimates) is undeniable.

C. OSHA Must Support Its Standards by "Substantial Evidence" after Consideration of the "Best Available" Evidence, Including "the Latest Available Scientific Data in the Field" and "Experience Gained Under This and Other Health and Safety Laws."

Although OSHA talks at length about the first sentence of Section 6(b)(5), its Brief and actions in this case effectively ignore the second and third sentences of that provision. But these two sentences are highly significant, since they embody Congress' commitment to setting standards on the basis of a specific evidentiary foundation, rather than on "views and arguments," as would have been permitted under the House Committee bill. This strong preference for standards based on evidence rather

[71] Accordingly, there is no merit to OSHA's contention that the decision below results in a "topsy-turvy" construction of the Act. OSHA Br. 58. Nor is there any substance to OSHA's argument that the decision below undercuts what it calls the "non-material impairment criterion" of Section 6(b)(5). OSHA Br. 38. There is no such absolute "criterion," for as we have already shown, Congress wanted to eliminate impairment of health *only* "to the extent feasible" and *only* if the risk of such impairment is "material." *See* pp. 38-40, 42-47, *supra*.

In addition, OSHA's claim that the variance provisions of the Act (29 U.S.C. § 655(d)) somehow make "the statute 'cost effective' " OSHA Br. 9 n.7. is completely beside the point. As OSHA itself implicitly concedes, the variance provisions have nothing to do with the "level of protection" to be provided by a

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than on theories and assumptions is buttressed by the Conference Committee's inclusion of the more rigorous "substantial evidence" review standard.

One of the most controversial features of the bill reported by the House Committee was a provision allowing the Secretary of Labor to establish occupational safety and health standards after notice-and-comment rulemaking and an informal hearing, based on "any evidence, data, views and arguments submitted in connection with the hearing . . . ."[72] This provision was sharply denounced by legislators in both houses, who warned against the "substantial financial impact" of allowing standards to be based on " 'views and arguments' rather than probative evidence." Leg. Hist. 884. *See* Add. B 3b-4b, 6b-7b, 12b, 18b, *infra*.[73]

The Senate Committee eventually resolved this concern by addition of the second and third sentences of Section 6(b)(5). These requirements, applicable to both safety and health standards,[74] provide as follows:

> Development of such standards *shall* be based on *research, demonstrations, experiments*, and such other information as may be appropriate. In addition to the attainment of the highest degree of health

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standard. *Id.* The most that can be said for this argument is that the variance provisions allow a few employers to find more "cost-effective" ways to achieve a level of production which —under OSHA's view of Section 6(b)(5)—may produce minimal benefits at enormous cost (regardless of how compliance is achieved).

[72] H. R. 16785 § 7, Leg. Hist. 728-30.

[73] For example, the dissenting views of minority members of the House Committee charged that there was "[n]o reason" for "this deviation from regular and fair procedures," and that under the Committee bill, "[t]he requirements that administrative decisions be based on facts and sound reasons mean little. . . ." Leg. Hist. 884. The strength of the House Committee minority was so great that their substitute bill, rather than the Committee's bill, eventually passed the full House. Add. B 18b, *infra*.

[74] *See* pp. 48-50 & n.70, *supra;* Add. B 17b, n.18, *infra*.

> and safety protection for the employee, other considerations shall be *the latest available scientific data in the field*, the *feasibility of the standards, and experience gained under this and other health and safety laws.*
> (emphasis added)

Congress could hardly have chosen language more clearly designed to insure that standards would be based on the best available factual evidence rather than on "views and arguments." Thus, the second sentence requires that OSHA standards be developed and based upon scientific information such as "research, demonstrations, [and] experiments." And the third sentence directs OSHA to utilize "the latest available scientific data in the field" as well as "experience gained under this and other health and safety laws." Clearly, these words contemplate that OSHA will give careful consideration to "demonstrations" such as those pertaining to risks and benefits, and to the "experience [of] other" health and safety agencies that have successfully used such techniques and demonstrations. *See* pp. 73-75, *infra*.

Even these requirements, however, did not fully allay the concerns of those who feared that the Secretary of Labor would impose arbitrary and unjustified burdens on employers. Add. B 3b-4b, 12b, 18b, *infra*. The crux of this concern was that, even though the Secretary was required to base his standards on factual evidence rather than "views and arguments," employers' judicial remedies were inadequate under the bills reported by the House and Senate Committees. As stated by Senator Cook, under the "arbitrary and capricious" test provided in those bills, "it will be very, very strange if they can

ever win a case." Leg. Hist. 343-44.[75] Indeed, this was one of the chief concerns that led the full House to reject the bill reported by the Committee and to pass a substitute bill which vested standard-setting authority in an independent board, based on formal rulemaking procedures with review under the "substantial evidence" test. Add. B 18b & n. 19, *infra*.

In Conference, the House finally withdrew its insistence on an independent standard-setting board, but only in return for retention of the more rigorous "substantial evidence" review test. This, it was believed, would protect against the possibility that the Secretary would regulate in an arbitrary and unfair manner. As summarized by Representative Steiger, the floor leader for the bill passed in the House:

> The Secretary's standard will only be sustained by the court if it is supported by 'substantial evidence on the record considered as a whole.' Thus, the Secretary must have a record on which to base his findings and to serve as the basis for judicial review. The act does not provide for an independent board for standard-setting as did the House bill. However, court review based upon substantial evidence provides a sufficient element of fairness to satisfy me that the conference report should be adopted.

Leg. Hist. 1218.[76]

[75] *See also* Leg. Hist. 344 (remarks of Senator Cook) ("they are just not going to win any lawsuits"); Add. B 3b-4b, 12b, *infra*.

[76] The courts have accepted that the "substantial evidence" review standard established by Section 6(f) represents a legislative compromise. As the Fifth Circuit observed, Section 6(f)

> accommodated the Senate's desire for administrative convenience and flexibility by accepting informal

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Accordingly, the addition of the "substantial evidence" review test is another indication that Congress intended standards under the Act to be based and reviewed, to the maximum degree possible, on evidence rather than on theories and assumptions. Far from excluding evidence pertaining to risks, benefits and costs, these provisions mean that "demonstrations" regarding such matters, as well as the experience of "other health and safety" agencies with the underlying techniques, are directly relevant to determining whether standards, such as the benzene standard, satisfy the substantive criteria of Section 6(b)(5) and are consistent with the relative overall health and safety objectives of the Act.

D. OSHA's Halting and Confused "Interpretation" Is Entitled to No Deference by the Court, Especially in Light of the Contrary Construction of the Occupational Safety and Health Review Commission.

Having addressed few of the statutory terms and little of the legislative history discussed above, OSHA falls back to a plea that this Court should accord "substantial deference" to "the Secretary's consistent and well-articulated construction of the Act." OSHA Br. 73. But, in fact, OSHA's "construction"

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> rulemaking procedures, but placated House concern for protection of employers from arbitrary burdens imposed by a massive federal bureaucracy, but [sic: by] adopting the substantial evidence test for judicial review.

Florida Peach Growers Ass'n v. Department of Labor, 489 F.2d 120, 128 (5th Cir. 1974), *citing* Associated Indus. of New York State, Inc. v. Department of Labor, 487 F.2d 342 (2d Cir. 1973).

has been neither "consistent," nor "well-articulated," nor even thoroughly-considered, and, as such, is entitled to no special weight. Moreover, it conflicts with the far more logical and faithful construction of the Act adopted by the Occupational Safety and Health Review Commission ("OSHRC" or "Review Commission") which Congress established as a check on abuses of power by OSHA. Add. B. 3b-4b, 12b-13b, 19b, *infra*.

As OSHA implicitly concedes, an agency's statutory interpretation is never entitled to unqualified deference by a reviewing court. This Court, and not OSHA, has the "ultimate responsibility to construe the language employed by Congress." *Zuber v. Allen*, 396 U.S. 168, 192-93 (1969).[77] Although an agency interpretation may, in some circumstances, be influential, the weight to be accorded depends upon

> the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all of those factors which give it power to persuade, if lacking power to control.

Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944).[78]

[77] *Accord*, SEC v. Sloan, 436 U.S. 103, 118 (1978); ("[T]he existence of a prior administrative practice, even a well-explained one," does not relieve the Court of its "responsibility to determine whether that practice is consistent with the agency's statutory authority."). As this Court recently noted, many decisions in which it has "deferred" to agency interpretations have not been based on deference at all, but rather on the Court's "own 'analysis of the structure and legislative history' " of the statute involved. Adamo Wrecking Co. v. United States, 434 U.S. 275, 287 n.5 (1978), *quoting* Train v. NRDC 421 U.S. 60, 86 (1975).

[78] *See also* Adamo Wrecking Co. v. United States, *supra*, 434 U.S. at 287-88; SEC v. Sloan, *supra*, 436 U.S. at 118.

OSHA's present construction of the Act lacks the "power to persuade" in all relevant respects. For one thing, the agency has not articulated a long-standing and consistent interpretation of the statutory provisions at issue here. Indeed, not once in its entire eight-year history has OSHA ever attempted a comprehensive and integrated construction of Sections 2(b), 3(8) and 6 of the Act. Nor has it done so in the cryptic, self-contradictory Federal Register notice issued in this case. *See* pp. 21-24, *supra*.[79]

Moreover, OSHA itself hedges about claiming that its construction has been consistent (OSHA Br. 72-73), and for good reason. As elaborated in Addendum C, OSHA's principal spokesperson recently testified that "incremental cost-benefit analyses" are a "key factor" in OSHA's standard-setting. Add. C 12c-13c & n. 33, *infra*. And, in an attempt to justify its standards for lead and cotton-dust under Section 6(b)(5), OSHA purported to perform elaborate analyses of the health benefits (reduced blood-lead levels in the case of lead, reduced incidence of "byssinosis" in the case of cotton-dust) expected from various alternative exposure levels. *See* Add. C 11c-12c, 14c, *infra*. Indeed, in the case of lead, OSHA went so far as to claim that its analysis satisfied the requirements of the decision below in this case. 43 Fed. Reg. 54354, 54431 (Nov. 21, 1978).

The inconsistency and confusion that have marked OSHA's interpretation of the Act have carried over even into its Petition and Brief to this

[79] As this Court has repeatedly observed, when the "Court can only speculate as to the [agency's] reasons for reaching the conclusion that it did, [the interpretation] obviously lacks the 'power to persuade' " and should not be accorded deference. SEC v. Sloan, *supra*, 436 U.S. at 118. *See also* Federal Maritime Comm'n. v. Seatrain, Inc., 411 U.S. 726, 745 (1973); Investment Co. Inst. v. Camp, 401 U.S. 617, 626-27 (1971).

Court. While OSHA's principal theme is that consideration of benefits and cost evidence is precluded by the Act, a far different position is suggested in the footnotes.

For example, both OSHA's Petition and Brief state in footnotes that: (i) use of risk assessment and cost-effectiveness techniques provides "very valuable" information regarding the costs of achieving various levels of health protection benefits (OSHA Br. 67 n.55); (ii) consistent with the Act, OSHA takes "the relative costs and benefits of the existing standards and the proposed standards into account" to "set priorities in the use of [its] own time and resources" (*id.* at 55 n.47); (iii) the Act permits OSHA to consider relative costs and benefits in deciding whether to propose a new standard for a toxic substance (OSHA Pet. 17 n.10); and (iv) risk assessments can and have been used in regulating non-carcinogens (OSHA Br. 67 n.55).

In light of these concessions, it is difficult to understand what is left of OSHA's case. To be sure, OSHA struggles valiantly to propose distinctions that would salvage its claim to a "consistent and well-articulated" interpretation of the Act. But the effort is wholly unconvincing. For example, it is hardly credible that Congress could have intended that information on relative costs and benefits—data that OSHA concedes are "very valuable" (*id.* 67 n.55)—may be taken into account to set priorities in the allocation of *OSHA's* resources (*id.* 55 n.47) but must be disregarded in deciding how to allocate the *societal* resources that are consumed by OSHA's standards.

Equally illogical is the notion that relative costs and benefits may be considered in deciding whether or not to adopt a new standard, but must be ignored in deciding what level of protection that standard should provide. OSHA Pet. 17 n.10; OSHA Br. 70-71. This is surely a distinction without a difference. Since the existing benzene standard limits exposure to 10 ppm, while the new standard would limit exposures to 1 ppm, the decision regarding the level of protection in the new standard is, in effect, a decision on whether or not to adopt a new standard at all.

By the same token, the distinction that OSHA seeks to draw between carcinogens and non-carcinogens has no basis in the Act. Nothing in Section 6(b)(5)—which applies to all toxic substances, carcinogenic and otherwise—indicates that risk and benefit evidence may be considered only in the case of non-carcinogens. The premise upon which OSHA's distinction rests is that there is "no safe level" for exposure to a carcinogen. OSHA Br. 67 n.55. But OSHA has taken the same "no safe level" position for non-carcinogens as well (*see, e.g.*, 43 Fed. Reg. 27350 (June 23, 1978) (cotton dust)) thereby rendering spurious the distinction upon which OSHA relies.

Moreover, any deference that might otherwise be due to OSHA's interpretation would be substantially undercut by the Review Commission's rejection of OSHA's extreme reading of the Act.[80] In the leading

[80] This Court has recognized that less deference is due to an agency interpretation of a statute where other agencies having responsibilities for administering the legislation have adopted a contrary view. *See* FCC v. American Broadcasting Co., 347 U.S. 284, 294-95 (1953) (The Court refused to adopt the FCC's definition of a statutory term where other affected agencies disagreed.).

case, *Continental Can Company*,[81] the Commission held that, in order "to effectuate the Congressional purposes underlying the Act," an OSHA noise standard requiring the installation of "feasible" engineering controls could be sustained only if the term "feasible" is applied so that "all the relevant costs and benefit factors [are] weighed."[82] OSHA had argued there, as it does here, that Section 6(b)(5) "requires employers to expend funds for each and every health hazard whether life threatening or not without limit so long as the expenditures for each hazard can be borne without putting the employers' financial condition in jeopardy."[83] The Review Commission rejected OSHA's position as "inconsistent with the intent of Congress," saying:

> Clearly, employers have finite resources available for use to abate health hazards. And just as clearly if they are to be made to spend without limit for abatement of this hazard their financial ability to abate other hazards, including life threatening hazards, is reduced.[84]

Accordingly, the Review Commission ruled that health standards must reflect a "priority for allocation of resources," so that worker health is maximized. The only way to accomplish this, the Commission held, is to consider "the costs which must be

[81] 4 BNA OSHC 1541, 1976-1977 CCH OSHD ¶ 21,009 (1976).

[82] 4 BNA OSHC at 1546-47, 1976-1977 CCH OSHD ¶ 21,009 at 25,255-56.

[83] 4 BNA OSHC at 1547, 1976-1977 CCH OSHD ¶ 21,009 at 25,256. *See* p. 31, *supra*.

[84] *Id.* The Commission added that, under OSHA's approach, "in some if not many cases [available resources] will be reduced to the point that [employers] will be put in financial jeopardy" in responding to other, more serious hazards. *Id.*

incurred and the benefits they will achieve."[85] This construction of the Act—which applies to *all* "toxic materials and harmful physical agents"—has since been consistently followed by the Commission.[86]

If deference is to be accorded to any administrative interpretation of the Act, the Review Commission's more logical and faithful view is entitled to greater regard than the inconsistent construction advanced by OSHA. This is particularly so since the Review Commission was purposely established by Congress as an independent agency with expertise comparable to OSHA's[87]—so that it could interpret

[85] *Id.*

[86] *See* Castle & Cooke Foods, a Div. of Castle & Cooke, Inc., 5 BNA OSHC 1435 1977-1978 CCH OSHD ¶ 21,854 (1977), *appeal docketed*, No. 77-2565 (9th Cir. July 14, 1977); Great Falls Tribune Co., 5 BNA OSHC 1433 1977-1978 CCH OSHD ¶ 21,844 (1977), *appeal docketed*, No. 77-2566 (9th Cir. July 14, 1977); West Point Pepperell, Inc., 5 BNA OSHC 1257, 1977-1978 CCH OSHD ¶ 21,751 (1977), *aff'd*, Marshall v. West Point Pepperell, Inc., 588 F.2d 979 (5th Cir. 1979); KLI, Inc., 6 BNA OSHC 1097 1977-1978 CCH OSHD ¶ (1977). *See also* n. 90 *infra*.

In only two cases has the Review Commission failed to apply the *Contental Can* rationale. The Commission's refusal in each case was based on the employer's failure to raise the issue. Both of these cases were reversed by the courts of appeals. Turner Co., Div. of Olin Corp., 4 BNA OSHC 1554, 1976-1977 CCH OSHD ¶ 21,023 (1976), *rev'd*, Turner Co. v. Secretary of Labor, 561 F.2d 82 (7th Cir. 1977); RMI Co., 6 BNA OSHC 1523, 1978 CCH OSHD ¶ 22,674 (1978), *rev'd*, RMI Co. v. Secretary of Labor, 594 F.2d 566 (6th Cir. 1979).

[87] Section 12(a) of the Act requires that the Commission be composed of three members who are "qualified" "by reason of training, education, or experience." 29 U.S.C. § 661(a). The courts have recognized the Review Commission's special expertise on occupational safety and health matters. *See, e.g.*, Southern Ry. v. OSHRC, 539 F.2d 335, 337-38 (4th Cir.), *cert. denied*, 429 U.S. 999 (1976).

the Act[88] and rule on the statutory validity of standards in the context of enforcement proceedings.[89]

Significantly, the Review Commission's construction has been upheld by the courts. For example, in *Turner Co. v. Secretary of Labor*, 561 F.2d 82 (1977), the Seventh Circuit adopted the Review Commission's *Continental Can* rationale in another noise case where OSHA interpreted the standard as requiring the use of expensive engineering controls instead of personal protective equipment (earplugs). The Court found that, after "thorough consideration of the . . . legislative history," the Review Commission in *Continental Can* had given the term "feasible" a construction that "is in accord with the clear intent of Congress and the purpose of the Occupational Safety and Health Act." 561 F.2d at 83, 85. Accordingly, the Court ruled that the "Commission must . . . determine whether the health benefits to employees who are already equipped with personal protection equipment justify the $30,000 cost to Turner for engineering controls."[90]

[88] International Union (UAW) v. OSHRC, 557 F.2d 607, 611 (7th Cir. 1977); Atlantic & Gulf Stevedores, Inc. v. OSHRC, 534 F.2d 541, 550-51 (3d Cir. 1976); Brennan v. Giles & Cotting, Inc., 504 F.2d 1255, 1261-62 (4th Cir. 1974). As the courts and commentators have pointed out, giving OSHA the sole administrative responsibility to interpret the Act would emasculate OSHRC's adjudicatory powers. *See* Currie, *supra* n.50 at 1119; Brennan v. Giles & Cotting, Inc., *supra*, 504 F.2d at 1261-62.

[89] Atlantic & Gulf Stevedores, Inc. v. OSHRC, *supra*, 534 F.2d at 550-51.

[90] 581 F.2d at 86. The Fifth Circuit observed recently that the interpretation of "feasible" adopted by the Review Commission in *Continental Can* and approved by the Seventh Circuit in *Turner* "certainly comports with the plain import of the term." Marshall v. West Point Pepperell, Inc., 588 F.2d 979, 981 n.3 (5th Cir. 1979).

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More recently, in *RMI Co. v. Secretary of Labor*, 594 F.2d 566 (1979), the Sixth Circuit approved what it called a "cost-benefit analytical framework for determining the economic feasibility" of a standard. *Id.* 568. Relying on "Congressional intent derived both from the statutory scheme and language and legislative history of the Act," the court, adopting the Review Commission's *Continental Can* rationale, held that "the costs of the proposed controls [are] to be balanced against the proposed benefits flowing therefrom in order *that resources [will] be allocated in priority to the degree of harm established.*" *Id.* 572 (emphasis added).

In sum, there is no basis here for deferring to OSHA's latest construction of the Act. Neither the agency nor its lawyers have presented the Court with the sort of "thorough," "validly reasoned" and "consistent" construction that has "the power to persuade." *Skidmore v. Swift & Co.*, *supra*. Furthermore,

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OSHA claims that *Turner* does not apply to "non-life-threatening health hazards." OSHA Br. 42 n.35. But the reference in the *Turner* opinion upon which OSHA's claim rests (581 F.2d at 86) does not so limit the decision. Moreover, the Review Commission and OSHA itself consider noise exposure—the health hazard involved in *Turner*—to be a "harmful physical agent," which, like benzene, is governed by § 6(b)(5) of the Act. *See Continental Can*, *supra*, 1976-1977 CCH OSHD at 25255-56.

Furthermore, the Review Commission has applied its *Continental Can* rationale to standards which beyond any question involve life-threatening hazards. *See, e.g.*, Republic Granite Co., Inc., 4 BNA OSHC 1711, 1976-1977 CCH OSHD ¶ 21, 167 (1976) (silica dust); Worley Brothers Granite Co., 4 BNA OSHC 2042 (1977) (same). Indeed, a Review Commission administrative law judge recently applied *Continental Can* in vacating an OSHA citation for a "serious" violation of the current 10 ppm benzene standard. Texaco Inc. and Oil, Chemical & Atomic Workers Union, 1978 CCH OSHD. ¶ 23,068 (1978) (OSHRC review pending). Further, the Sixth Circuit's decision in *RMI*, which reaffirmed *Turner*, relied on the decision below and other cases involving life-threatening hazards. 594 F.2d at 571-72.

the extreme reading of the Act advanced by OSHA's lawyers here has been rejected consistently by the Review Commission, whose more reasonable interpretation has been sustained by the courts.

E. OSHA's Reading of the Act to Preclude Consideration of Risk, Benefit and Cost Evidence Is Inconsistent with the Weight of Relevant Precedent.

While the precise issues and arguments before the Court have not been raised or addressed elsewhere, the relevant case law lends more support to respondents' interpretation than it does to the extreme construction advanced by OSHA. Thus, the holdings of the Seventh Circuit in the *Turner* case and the Sixth Circuit in the *RMI* case are consistent with the decision below. Other courts, although not addressing the issue so directly, have taken a similar position.[91]

OSHA relies on other decisions—most notably *Industrial Union Dep't, AFL-CIO ("IUD") v. Hodgson*, 499 F.2d 467, 162 U.S. App. D.C. 331 (1974), *Society of the Plastics Industry ("SPI") v. OSHA*, 509 F.2d 1301 (2d Cir.), *cert. denied*, 421 U.S. 992 (1975), and *American Iron and Steel Institute ("AISI") v.*

[91] In Florida Peach Growers Ass'n v. Department of Labor, 489 F.2d 120, 130 (5th Cir. 1974), the court stated: "The promulgation of any standard will depend upon a balance between the protection afforded by the requirement and the effect upon economic and market conditions in the industry." Similarly, stressing that "the rule to be applied is one of reasonableness and feasibility," the Eighth Circuit, in United Parcel Service of Ohio, Inc. v. OSHRC, 570 F.2d 806, 812 (1978), overturned an order enforcing a safety standard because of the failure "to give consideration to less rigorous requirements" having less severe economic consequences.

OSHA, 577 F.2d 825 (3d Cir. 1978), *petitions for cert. pending*, 47 U.S.L.W. 3422 (U.S. Dec. 8, 1978) (Nos. 78-918 & 78-919)—which, as the court below noted, involved their own factual records. Pet. App. 21a (581 F.2d at 505). Whether or not these cases are consistent with the holding of the court below,[92] the fact is that the *IUD*, *SPI* and *AISI* courts were not called upon, as this Court is, to provide a coherent interpretation of the Act as an integrated whole, giving meaning to all of the relevant provisions.[93]

Moreover, looking beyond the cases interpreting the OSH Act, decisions construing closely similar health and safety legislation provide strong support for rejecting OSHA's arguments here.

One example is the Consumer Product Safety Act ("CPSA"), 15 U.S.C. §§2051, *et seq.*, which authorizes the adoption of consumer product safety rules that are "reasonably necessary to eliminate or reduce an unreasonable risk of injury."[94] This provision, as noted by the court below, has been construed to require the Consumer Product Safety Commission "to assess the expected benefits in light of the burdens to be imposed by the standard."[95] Since occupational

[92] For example, the court in *IUD* recognized that considerations apart from mere technological and financial capability—*e.g.*, the inpact on intra- and inter-industry competition—are relevant to determining whether a standard is "feasible" within the meaning of Section 6(b)(5). *See* 499 F.2d at 478.

[93] A good example of another statute so construed is this Court's recent decision in Southeastern Community College v. Davis, 47 U.S.L.W. 4689 (June 11, 1979).

[94] 15 U.S.C. § 2058(c)(2)(A).

[95] Pet. App. 17a (581 F.2d at 503), *citing* Aqua Slide 'N' Dive Corp. v. CPSC, 569 F.2d 831, 844 (5th Cir. 1978); D.D. Bean & Sons v. CPSC, 574 F.2d 643 (1st Cir. 1978).

safety and health standards also must be "reasonably necessary or appropriate to provide safe or healthful employment," 29 U.S.C. § 652(8), it is reasonable to conclude that Congress intended to impose a similar obligation upon OSHA.

OSHA quarrels with this analysis principally on the ground that the CPSA "permits regulation only of risks that are 'unreasonable'" (*i.e.*, where the trade-off between the risks and utility of a product argue in favor of control), while, in OSHA's view, the OSH Act calls for the elimination of all hazards, no matter how trivial the risk or how great the cost of control. OSHA Br. 46-47. But OSHA's purported distinction is invalid. The goal of safe and healthful workplaces under the OSH Act—like the concept of a "safe" drug under the Food, Drug, and Cosmetic Act—is itself a relative objective, comparable to the CPSA's goal of eliminating unreasonable risks. *See* pp. 35-38, *supra*. As in the case of consumer product safety rules, trade-offs are involved whenever OSHA allocates substantial resources to the reduction of one health and safety risk, leaving fewer resources to be devoted to the reduction of other workplace hazards.[96]

[96] OSHA also attempts to distinguish the OSH Act from the CPSA on the ground that the "reasonably necessary" language in the former appears "in a collateral definition" rather than "in the clause granting the power to regulate." OSHA Br. 46-47. This argument was properly rejected by the court below (Pet. App. 14a-15a (581 F.2d at 501-02)), since there is no logical reason why placement of the phrase in one provision of the Act rather than another makes any substantive difference. *See, e.g.*, Walling v. Portland Terminal Co., 330 U.S. 148 (1947) (definition of "employees" in Fair Labor Standards Act held to be determinative of the question of the agency's substantive authority).

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Absent an express bar, other health and safety statutes also have been read to require a consideration of risk, benefit and cost evidence. For example, the National Highway Traffic Safety Act provides for the adoption of "reasonable, practicable and appropriate" traffic safety standards.[97] This provision has been construed as requiring the Secretary of Transportation to "identif[y] some of the costs associated with the proposal and determine[] that these costs are overriden by reasonably predictable benefits."[98] Similarly, the Federal Water Pollution Control Act provision directing that EPA's 1983 effluent limitation guidelines reflect "the best available technology *economically achievable* . . . which will result in *reasonable further progress* toward the national goal of eliminating the discharge of all pollutants,"[99] has been held to require consideration by

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OSHA also attempts to read Section 3(8) as if it were as broad as the "Necessary and Proper" Clause in the Constitution, citing cases which OSHA claims support an interpretation of Section 3(8) as allowing "the Secretary to issue any standard that he rationally concludes is appropriate." OSHA Br. 46. But none of the cases cited by OSHA involve statutes which contain the expression "reasonably necessary." Where Congress has used that language, as in CPSA, it has been construed in a manner consistent with the decision below. *See* p. 66 & n. 95, *supra*.

[97] 15 U.S.C. § 1392(f)(3).

[98] H & H Tire Co. v. Department of Transportation, 471 F.2d 350, 356-57 (7th Cir. 1972) (Stevens, J., concurring opinion adopted by the court) (footnotes omitted).

[99] 33 U.S.C. § 1311(b)(2)(A) (emphasis added).

EPA of "the benefits derived from the application of its effluent reduction requirements. . . ."[100]

In the same vein, the general safety clause of the Food, Drug, and Cosmetic Act has, as discussed above, been given a pragmatic construction allowing for the evaluation of benefits—except where the categorical and absolute prohibition of the Delaney Clause applies. *See* p. 36 & n. 49, *supra*. A similar approach was taken in construing the pre-1972 provision of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), which required EPA to deny (or withdraw) the registration of a pesticide if its use was "injurious to living man."[101] Although this statutory language did not expressly require consideration of benefits, the courts consistently recognized the obvious trade-offs involved and asked EPA to balance the benefits of restricting use of pesticides against the costs of doing so.[102]

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[100] Appalachian Power Co. v. Train, 545 F.2d 1351, 1361 (4th Cir. 1976). The fact that "some benefit" could be assumed to result from a reduction in the discharge of heat was held to be insufficient to satisfy the statutory provision. Rather, the court held that EPA must show what ecological benefits would result from the reduction in heat and compare the cost of achieving those benefits "with the benefits and costs associated with alternative levels of heat reduction." *Id.* 1364.

[101] 7 U.S.C. §§ 135(z)(2), (g) & (h), 135b (1970).

[102] *See, e.g.*, Environmental Defense Fund, Inc. v. Ruckelshaus, 439 F.2d 584, 594, 142 U.S. App. D.C. 74, 84 (1971) (holding that the decision to cancel the use of a pesticide "does not turn on a scientific assessment of hazard alone," and emphasizing that "[t]he statute leaves room to balance the benefits of a pesticide against its risk"); Environmental Defense Fund, Inc. v. EPA, 465 F.2d 528, 536, 150 U.S. App. D.C. 348, 356 (1972) (pre-1972 FIFRA provision required "a complex administrative calculus, in which the 'nature and magnitude of the foreseeable hazards associated with use of a particular

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In sum, the courts have construed other health and safety legislation in a pragmatic and relative manner, giving due regard to the overall objectives of the statutes and the practicalities of regulatory decision-making. In the absence of absolute statutory commands such as the Delaney Clause or the Endangered Species Act, the courts have rejected the tunnel-vision approach advocated by OSHA here, and instead have recognized that regulations should be based upon the best available information concerning what they will achieve and what they will cost.

II. THE COURT BELOW CORRECTLY SET ASIDE OSHA'S BENZENE STANDARD BECAUSE OSHA VIOLATED THE ACT'S STANDARD-SETTING REQUIREMENTS AND BECAUSE OSHA'S "APPRECIABLE BENEFITS" DETERMINATION WAS NOT SUPPORTED BY "SUBSTANTIAL EVIDENCE."

In light of the court's opinion and the preceding discussion of the Act's requirements (pp. 31-69), the reasons for affirmance of the decision below do not require lengthy elaboration. The court relied upon each of the provisions of the Act discussed above, and although its treatment was understandably not as exhaustive as the briefs before this Court, its basic holding is unassailable: OSHA must set standards that are reasonable and practical, and in order to do so, it must identify, at least roughly, the benefits that

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product' are weighed against the 'nature of the benefit conferred' by its use."); Stearns Elec. Paste Co. v. EPA, 461 F.2d 293, 307 (7th Cir. 1972) (Stevens, J.) (reaffirming the D.C. Circuit's interpretation of pre-1972 FIFRA provision as requiring a "delicate balance of [a pesticide's] benefits against its adverse effects").

each standard is expected to achieve and to consider those benefits in light of the costs imposed by the standard. Only if this is done can OSHA carry its "affirmative burden [of] demonstrat[ing] the reasonableness of [its] adopted standard."[103]

Without reaching the ultimate question of whether there is a "reasonable relationship" between the expected benefits and costs of OSHA's benzene standard (pp. 24-27 & nn. 44, 45, *supra*), the court below ruled that OSHA must make at least a "rough but educated estimate[ ] of the extent of benefits expected from reducing the permissible exposure limit from 10 ppm to 1 ppm." Pet. App. 21a (581 F.2d at 504). And that determination, like any determination under the Act, must be supported by "substantial evidence." *Id.* 18a (581 F.2d at 503). For where, as in this case, "the facts underlying the Secretary's determinations are susceptible of being found in the usual sense, that must be done, and the reviewing court will weigh them by the substantial evidence standard."[104]

[103] Atlantic & Gulf Stevedores, Inc. v. OSHRC, 534 F.2d 541, 551 (3d Cir. 1976). *Accord*, Associated Indus. of New York State, Inc. v. Department of Labor, *supra*, 487 F.2d at 351-53.

[104] Industrial Union Dep't, AFL-CIO v. Hodgson, *supra*, 499 F.2d at 474. *See also* Synthetic Organic Chem. Mfrs. Ass'n v. Brennan, 503 F.2d 1155, 1160 (3d Cir. 1974), *cert. denied*, 420 U.S. 973 (1975) (The substantial evidence standard applies whenever the agency's determination is "based in whole or in part on factual matters subject to evidentiary development."). In addition to this case, a number of other OSHA standards have been set aside for failure to satisfy the substantial evidence requirement. *See, e.g.*, Industrial Union Dep't, AFL-CIO v. Hodgson, *supra*, 499 F.2d at 479-81; Florida Peach Growers Ass'n, Inc. v. Department of Labor, *supra*, 489 F.2d at 129-32; Associated Indus. of New York State, Inc. v. Department of Labor, *supra*, 487 F.2d at 351-54.

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The approach taken by OSHA in this case stands the Act on its head. Rather than looking first at what benefits, if any, a reduction of the permissible exposure limit would achieve, OSHA simply chose a number (1 ppm) and then set about showing that the affected industries could achieve that limit and still survive financially. After being confronted with uncontradicted evidence that its standard would achieve very little (if anything), OSHA felt compelled to mention the question of benefits in some fashion in its final Federal Register notice. But then, it did no more than proclaim summarily that its standard would produce "appreciable benefits"—without citing a shred of evidence in support of that determination. In short, OSHA's benzene standard is almost a textbook example of how not to regulate under the Act, and, accordingly, it was properly set aside by the court below.

A. The Court Below Correctly Held That OSHA Failed to Comply with the Standard-Setting Requirements of the Act.

The court below vacated OSHA's standard based on a combined reading of Sections 2(b), 3(8) and 6(b) of the Act. As interpreted by the court, these

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Indeed, even where OSHA shows that it is unable to make a factual determination because of the absence of evidence (a showing not made here), the courts have subjected the agency's explanation of its action to "exacting scrutiny" (Industrial Union Dep't, AFL-CIO v. Hodgson, *supra*, 499 F.2d at 475) in order to ensure that OSHA has acted "in a manner reasonable under the state of the record before [it]." Florida Peach Growers Ass'n v. Department of Labor, *supra*, 489 F.2d at 129. *See also* Associated Indus. of New York State, Inc. v. Department of Labor, *supra*, 486 F.2d at 349-50; Synthetic Organic Chem. Mfrs. Ass'n v. Brennan, *supra*, 503 F.2d at 1159-60. *Cf.* Appalachian Power Co. v. Train, *supra*, 545 F.2d at 1365.

provisions deprive OSHA of "the unbridled discretion to adopt standards designed to create absolutely risk-free workplaces regardless of cost," and require OSHA to base its standards on "a number of pragmatic limitations" including "feasibil[ity]" and "specific kinds of information OSHA must consider in enacting standards." Pet. App. 15a-16a (581 F.2d at 502). Since we have already treated these provisions in detail, all that is required here is to summarize why the decision below was eminently sensible in light of these requirements and the record in this case.

Given OSHA's insistence that it may require the expenditure of whatever resources are necessary to reduce benzene exposures to 1 ppm (so long as the survival of the industries affected is not jeopardized), one might assume that benzene is the only workplace hazard with which the agency need be concerned. But, in fact, there are a multitude of potential occupational carcinogens that exhibit wide variations both in potency and in the conditions of workplace exposure.[105] What is more, these substances constitute only a fraction of the aggregate health and safety risks of varying severity present in the workplace and environment.

[105] As noted above (p. 4 n.5, *supra*), NIOSH has already identified approximately 2000 potential occupational carcinogens, many of which may ultimately be the subject of OSHA standards. These substances exhibit wide variations in carcinogenic potency. For example, aflatoxin, a powerful carcinogen present in consumer peanut products at tolerance levels set by FDA, is about 100,000 times more potent than benzene. A. 79-80; 39 Fed. Reg. 42748 (December 6, 1974). *See also* Add. C. 3c-4c & n. 7, *infra*.

Since the societal resources that can be devoted to these health and safety risks are not unlimited,[106] it is hardly surprising that the Act requires OSHA to identify, at least roughly, what its standards will accomplish.[107] That is, of course, what Congress intended when it required that standards be "feasible," and that they address "material" rather than inconsequential risks. For as Dr. Zeckhauser testified, the congressional objective of assuring the most adequate overall health and safety protection for employees can never be accomplished unless OSHA makes "a conscientious effort to determine what proposed policies will cost us, and what they will achieve for us." A. 136.

Examples of the kinds of "demonstrations" that would enable OSHA to make the "rough but educated estimate[]" of benefits required by the Act are the

[106] As noted in *Making Prevention Pay, the Final Report of the Interagency Task Force on Workplace Safety and Health*, p. VII-15 (1979):

> The cost of complying with OSHA is only part of the cumulative impact of Federal regulation on individual firms and their industries. There is growing concern that these cumulative impacts are costing jobs and draining substantial investment from new efforts at industrial innovation, while adding perhaps ¾ of 1% to the yearly rate of inflation. (Footnotes omitted.)

[107] As the Department of Health, Education and Welfare stressed in its departmental critique of OSHA's proposed standard; "real world pragmatism requires a systematic decision-making process" that takes account of the enormous variation in potencies and exposure patterns of cancer-causing agents. Letter of Charles Custard, Director of HEW Office of Environmental Affairs, dated July 12, 1977 (Exh. 205.A).

risk assessments prepared by Dr. Wilson and EPA. The usefulness of such "demonstrations" in standard-setting is proved by the "experience gained under this and other health and safety laws" —"experience" that OSHA is expressly directed to consider in formulating standards under Section 6(b)(5).

Specifically, as discussed in the record[108] and amplified in Addendum C, risk estimation techniques such as those employed by Dr. Wilson and EPA are used in decision-making by virtually every other federal health and safety agency, including the Environmental Protection Agency, the Food and Drug Administration, the Consumer Product Safety Commission, the National Highway Traffic Safety Administration, and the Nuclear Regulatory Commission. These agencies have found, in the words of EPA, that the use of risk assessment techniques in regulating carcinogens represents "a significant step toward the objective of achieving real benefits in improved public health while avoiding the burden of undesirable regulatory action." 41 Fed. Reg. 21402, 21403 (May 25, 1976). *See* Add. C 8c-11c, *infra*.[109]

[108] *E.g.*, A. 42-45, 82, 159; API Post-Hearing Br. 92-93 (Exh. 217-33).

[109] If any further confirmation of the utility of these techniques were needed, it is found in the strong endorsements of groups as diverse as the National Academy of Sciences, the Interagency Regulatory Liaison Group (of which OSHA is a member), the President's Science Advisors and President's Council on Wage and Price Stability. Add. C 2c-7c, *infra*. Curiously, following the decision below, OSHA has not only publicly supported risk assessment techniques for evaluating the cost-effectiveness of its standards, but has gone so far as to employ such analyses in adopting and justifying standards for other toxic substances under Section 6(b)(5). *See* p. 57, *supra*; Add. C 11c-14c, *infra*.

In short, this "experience gained" under "other health and safety laws" imposes a heavy burden—which OSHA never undertook in its Federal Register notice—of explaining why it could not follow the example of other agencies that use "demonstrations" such as those provided by Dr. Wilson and EPA. On this record, therefore, the decision below should be affirmed even without reference to the other standard-setting requirements relied upon by the court. But when these other requirements, including the "reasonably necessary" provision of Section 3(8) and the "feasibility" and other "pragmatic limitations" of Section 6(b)(5), are taken into account, it becomes even more apparent that OSHA simply failed to adopt a standard that is based on "the best available evidence" concerning the reasonableness and practicality of reducing benzene exposures to 1 ppm.

B. The Court Below Correctly Held That OSHA's "Appreciable Benefits" Determination Was Not Supported by "Substantial Evidence" or Even a Rational Explanation.

As discussed above (pp. 17-21, *supra*), this is not a case where there was no evidence on the extent of benefits expected to result from OSHA's standard. Dr. Richard Wilson submitted a preliminary risk assessment for benzene based upon the very studies (particularly the Infante Study) cited by OSHA to establish an association between benzene exposure and an excess incidence of leukemia. Although Dr. Wilson employed a series of assumptions designed to

overstate the hazard,[110] his analysis indicated that the risk presented by benzene exposures of 10 ppm is exceedingly small, if it exists at all.

For example, Dr. Wilson estimated that the annual risk of cancer mortality faced by an employee exposed to benzene levels of 10 ppm is approximately the same as the additional cancer risk faced by a person who takes one round-trip transcontinental plane flight a month,[111] or who drinks slightly more than one cup of chlorinated tap water (or a beverage made from chlorinated tap water) each day.[112]

Three months later (and long before OSHA issued its final standard), Dr. Wilson's preliminary risk estimate was supported by the results of an entirely independent demonstration prepared by EPA. A. 14-29. Like Dr. Wilson's analysis, the EPA risk assessment was based largely on Dr. Infante's data

[110] For example, Dr. Wilson assumed that there is no threshold level for benzene-related leukemia, and he computed the risk of low level exposure on the basis of the most conservative linear extrapolation model. A. 164. In addition, Dr. Wilson doubled his risk estimate by assuming—without any real need to do so (*see* A. 33-34)—that one case of cancer will occur for each case of leukemia predicted by his model. A. 171.

[111] *See* A. 174. The plane-flight cancer risk is the result of exposure to cosmic radiation. Each one-way transcontinental flight presents an increased risk comparable to the additional hazard of an employee working at benzene levels of 10 ppm for two weeks.

[112] This risk results from the fact that chlorinated water may contain chloroform, a carcinogen. Each gallon of chlorinated drinking water that is consumed presents an increased risk comparable to the additional hazard to an employee who works at benzene levels of 10 ppm for two weeks. A. 174. A person drinking slightly more than one cup per day would consume two gallons within a two-week period.

and assumed a "linear non-threshold" dose-response relationship in order to obtain "an upper limit to the estimated risk." A. 15. Although OSHA produced the EPA report in an attempt to discredit Dr. Wilson's demonstration, an analysis of the EPA study showed that Dr. Wilson's estimate, if anything, overstated the maximum risk at 10 ppm and overestimated the maximum benefits of a reduction to 1 ppm. *See* p. 21, *supra*.[113]

But even if one insists that only Dr. Wilson's more conservative upper bound estimate should be used, *i.e.*, that the standard would prevent at most one case of leukemia and one other cancer every six years (see p. 20, *supra*), the benefits of the standard cannot reasonably be deemed to be "appreciable" without consideration of how the same resources might otherwise be allocated. For example, if the three billion dollar annual budget of the National Institutes of Health ("NIH")[114] were administered with the level of effectiveness represented by OSHA's benzene standard, NIH could expect to save little

[113] In light of this analysis, OSHA now attempts to discredit the EPA demonstration (which it submitted approvingly to the court below) by distorting its findings and asserting that the Infante data (on which EPA's analysis is based and on which OSHA relied in promulgating the standard) are "too imprecise to establish a dose-response relationship." OSHA Br. 70 n.56. In fact, while EPA acknowledged some margin for error, it stressed that the model it chose was "expected to give an *upper limit* to the estimated risk," and concluded that the actual risk "is not likely to be higher" than its estimate, "but it could be lower." A. 15, 16.

[114] THE BUDGET OF THE UNITED STATES GOVERNMENT—FISCAL YEAR 1980, 418 (1979).

more than ten lives per year.[115] Indeed, the evidence indicates that if all of society's resources were allocated with the cost-ineffectiveness of the benzene standard, the total gross national product would soon be exhausted without making even a minor dent in the vast array of health and safety problems confronting workers and others in our society. A. 175-76.

As discussed above (pp. 17-20, 71-75), the studies prepared by Dr. Wilson and EPA are examples of the type of evidence that should underlie an occupational health standard. Yet, OSHA presented no evidence demonstrating that Dr. Wilson's assessment (as supported by the results of the EPA demonstration) was inaccurate. Only in its final Federal Register notice did the agency deign to address the question of benefits at all, and then only to proclaim that the benefits are "likely to be appreciable." Nowhere did OSHA offer any evidence, or even a rational explanation, in support of this "appreciable" benefits "determination"—even though it is directly contradicted by the Wilson and EPA risk estimates.

In a series of legally irrelevant, *post-hoc* rationalizations,[116] OSHA's lawyers belatedly attempt to supply the explanation that the agency itself failed

[115] Dr. Wilson concluded, based on cost estimates developed by Arthur D. Little, that OSHA's standard would save two lives every six years at a cost of $300 million per life saved. A. 81. While this figure may be adjusted downward slightly in light of OSHA's final cost estimates (n.40, *supra*), NIH's $3 billion budget would be exhausted shortly after saving the tenth life if spent at the rate of the OSHA benzene standard.

[116] This Court has repeatedly emphasized that the *post-hoc* rationalization of counsel is entitled to no weight. *See, e.g.*, FPC v. Texaco Inc., 417 U.S. 380, 397 (1974); SEC v. Chenery Corp., 332 U.S. 194, 196 (1947).

to provide. But even when OSHA's own statements and the *post-hoc* rationalizations of its lawyers are viewed most charitably, they fail to justify the agency's action or to satisfy the "substantial evidence" requirement of Section 6(f) of the Act.

First, OSHA's lawyers claim that risk estimation techniques are too imprecise to be useful, citing (i) uncertainties in extrapolating from animal studies to humans, (ii) difficulties in determining the exposure levels involved in epidemiologic studies upon which extrapolations are based, and (iii) lack of assurance that an accurate dose-response extrapolation model has been selected. OSHA Br. 65-70. Even if these criticisms had any merit generally, they plainly do not apply here, where (i) interspecies extrapolation is unnecessary because the underlying evidence consists of human studies, (ii) the exposure levels in the relevant studies can be fixed within a reasonable range, and (iii) uncertainties about the dose-response function were resolved by utilizing the most conservative extrapolation models.[117]

Moreover, as attested by the witnesses below and the agencies that use risk estimation techniques, the inability to attain precision does not detract from the fact that even "rough but educated estimates" of the

[117] For this reason, the repeated references to the 5 million-fold variation in predicted risks from saccharin consumption (NRDC Br. 15, 23) have no relevance here. If anything, the fact that the most conservative extrapolation models may overstate human cancer risks supports the conclusion that the risk estimates of Dr. Wilson and EPA (which employed the most conservative assumptions) are probably greatly overstated.

degree of risk prevented can be of "immense value." A. 144. *See* pp. 20, 73-75, *supra*; Add. C 2c-11c, *infra*.[118]

Equally irrelevant is OSHA's argument that any estimate of health benefits must be rejected out-of-hand because OSHA is not permitted to value human life. OSHA Br. 62 n.52. In fact, no such valuation need be made. *See* p. 19, *supra*; Add. C 7c, *infra*. Nevertheless, identification and assessment of the degree of risk prevented (*i.e.*, the benefits) is essential if the most adequate overall protection is to be provided, since, in words of the President's Council, "OSHA is faced with a finite quantity of society's resources or maximum costs that can be allocated to worker safety and health in any industry." A. 126.

Finally, OSHA's rejection of Dr. Wilson's risk assessment for benzene on the ground that it was inconsistent with the results of the Infante Study (Pet. App. 161a-162a) simply makes no sense. In fact, as discussed above, Dr. Wilson's estimate was largely based on Dr. Infante's findings, as was the subsequent, confirmatory demonstration provided by EPA.[119]

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[118] As OSHA implicitly acknowledges, once an appropriate extrapolation model is selected, all of the relevant data points along the line between high level exposure and very low level exposure can be determined. OSHA Br. 64 n.53. Consequently, contrary to OSHA's implication (*id.* 64), a requirement that OSHA assess the benefits that would be expected from appropriate segmental reductions in permissible exposure levels would not create any additional burden for the agency.

[119] In support of its outright rejection of Dr. Wilson's demonstration, OSHA's Federal Register notice observes only that the Infante Study "disclosed seven excess leukemia deaths in a population of about 600 people over a 25-year period." Pet. App. 161a. What OSHA fails to disclose (if, indeed, it ever considered comparing Infante's and Wilson's results) is that Infante's findings are equivalent to slightly *less* than 2 cases every six years. Dr. Wilson reached approximately the same result in applying the Infante data to a worker population which, while larger (30,000), is exposed to far lower benzene levels (considerably less than 10 ppm on the average, instead of 100 ppm as in the Infante Study).

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In sum, neither OSHA nor its lawyers have managed to articulate any rational explanation for rejecting the best available evidence regarding benefits in the present case, or for OSHA's failure to make any attempt to estimate the benefits of the standard on its own. The fact is that OSHA simply chose to "bury[ ] its head in the sand."[120] It identified no evidence supporting its summary "determination" that the benefits of its standard are "likely to be appreciable" (Pet. App. 162a), and was unable to explain how such a conclusion could be squared with the evidence pointing in the opposite direction.[121] Far from being supported by substantial evidence, OSHA's "appreciable benefits" determination rests upon nothing more than a "conclusory statement

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OSHA's lawyers provide other *post-hoc* rationalizations for rejecting Dr. Wilson's estimates (OSHA Br. 69 n.56) which also lack foundation. Thus, rather than underestimating the number of workers exposed to benzene levels below 10 ppm, as OSHA claims, Dr. Wilson based his estimate upon the number of such workers provided by OSHA's own contractor, A.D. Little—an estimate that OSHA never disputed and which its lawyers cite with approval (*id.* 24 n.26). And, far from giving "no basis for his conclusions at the hearing" (*id.* 69 n.56), Dr. Wilson carefully detailed the basis and rationale for his estimate in his direct testimony and during three hours of cross-examination by OSHA, and union representatives. Tr. 2717-2827.

[120] Testimony of Dr. Richard Zeckhauser, A. 47. Dr. Roy Albert, the Head of EPA's Carcinogen Assessment Group (*See* Add.C 8c-9c, *infra*) has agreed with Dr. Zechauser that OSHA's approach of ignoring risk assessment is "like the ostrich putting its head in the sand." Carter, *Dispute Over Cancer Risk Quantification*, 203 SCIENCE 1324, 1325 (March 30, 1979).

[121] All it could offer was a policy assumption that "exposure to lower levels is accompanied by a reduced risk . . . ." Pet. App. 160a. However, the record evidence indicated that the leukemia risk at an exposure level of 10 ppm was already minuscule and that a reduction of exposures to 1 ppm would yield only the most insignificant additional protection. Consequently, the assumption that lower exposures are accompanied by lower risks provides no justification whatsoever for a determination of "appreciable benefits" in the circumstances of this case.

of reasons,"[122] unsupported by a "scintilla" of evidence,[123] or even by a rationally articulated explanation of the course of action the agency chose to follow.[124]

To sustain OSHA's action on such a record, a reviewing court would have to sanction the development of occupational health and safety standards upon precisely the sort of unsubstantiated "views and arguments" that the substantial evidence requirement was intended to preclude. Consequently,

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[122] Dry Color Mfrs. Ass'n v. Department of Labor, *supra*, 486 F.2d at 106.

[123] *Cf.* Consolidated Edison Co. v. NLRB, 305 U.S. 197, 229 (1938). *See also* Consolo v. FMC, 383 U.S. 607, 619-20 (1966); May Trucking Co. v. United States, 593 F.2d 1349, 1352 (D.C. Cir. 1979).

[124] The importance of careful and rational articulation, even of policy determinations, has been emphasized repeatedly by this Court. *See, e.g.*, Baltimore & Ohio R.R. v. Aberdeen & Rockfish R.R., 393 U.S. 87, 91-92 (1968); NLRB v. Metropolitan Life Ins. Co., 380 U.S. 438, 442-43 (1965); Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 167-68 (1962); SEC v. Chenery Corp., 332 U.S. 194, 196-97 (1947). It has also been stressed by courts reviewing OSHA standards. *See, e.g.*, Industrial Union Dep't, AFL-CIO v. Hodgson, *supra*, 499 F.2d at 475-76; Synthetic Organic Chem. Mfrs. Ass'n v. Brennan, *supra*, 503 F.2d at 1159-60.

The articulation requirement established by basic principles of administrative law is underscored by statute and regulation on OSHA's case. Thus, Section 6(b)(8) of the Act requires that where, as here, OSHA adopts a standard which "differs substantially from an existing national consensus standard," OSHA's statement of reasons—required by Section 6(e), 29 U.S.C. § 655(e)—must explain "why the rule as adopted will better effectuate the purposes of this Act than the national consensus standard." 29 U.S.C. § 655(b)(8). OSHA's own procedural regulations amplify these requirements by providing that the statement of reasons must "show the significant issues which have been faced and . . . articulate the rationale for their solution." 29 C.F.R. § 1911.18(b).

OSHA's "appreciable benefits" determination, and the standard that rests upon that determination, were properly set aside by the court below.

CONCLUSION

The judgment of the court below should be affirmed.

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ADDENDUM A

STATUTORY PROVISIONS INVOLVED

Section 2(b) and paragraphs (3), (5), (6) and (7) thereof (29 U.S.C. § 651(b)(3), (5), (6) & (7)) provide as follows:

> The Congress declares it to be its purpose and policy, through the exercise of its powers to regulate commerce among the several States and with foreign nations and to provide for the general welfare, to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources—
>
> * * *
>
> (3) by authorizing the Secretary of Labor to set mandatory occupational safety and health standards applicable to businesses affecting interstate commerce . . . ;
>
> * * *
>
> (5) by providing for research in the field of occupational safety and health, including the psychological factors involved, and by developing innovative methods, techniques, and approaches for dealing with occupational safety and health problems;

(6) by exploring ways to discover latent diseases, establishing causal connections between diseases and work in environmental conditions, and conducting other research relating to health problems, in recognition of the fact that occupational health standards present problems often different from those involved in occupational safety;

(7) by providing medical criteria which will assure insofar as practicable that no employee will suffer diminished health, functional capacity, or life expectancy as a result of his work experience;

* * * *

Section 3(8) of the Act (29 U.S.C. § 652(8)) provides:

(8) The term 'occupational safety and health standard' means a standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment.

Section 6(b)(1) of the Act (29 U.S.C. § 655(b)(1)) provides:

(1) Whenever the Secretary, upon the basis of information submitted to him in writing by an interested person, a representative of any organization of employers

or employees, a nationally recognized standards-producing organization, the Secretary of Health, Education and Welfare, the National Institute for Occupational Safety and Health, or a State or political subdivision, or on the basis of information developed by the Secretary or otherwise available to him, determines that a rule should be promulgated in order to serve the objectives of this Act, the Secretary may request the recommendations of an advisory committee appointed under section 7 of this Act.

Section 6(b)(5) of the Act (29 U.S.C. § 655(b)(5)) provides:

(5) The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and

experience gained under this and other health and safety laws.

Section 6(b)(8) of the Act (29 U.S.C. § 655(b)(8)) provides:

> (8) Whenever a rule promulgated by the Secretary differs substantially from an existing national consensus standard, the Secretary shall, at the same time, publish in the Federal Register a statement of the reasons why the rule as adopted will better effectuate the purposes of this Act than the national consensus standard.

Section 6(e) of the Act (29 U.S.C. § 655(e)) provides:

> (e) Whenever the Secretary promulgates any standard, makes any rule, order, or decision, grants any exemption or extension of time, or compromises, mitigates, or settles any penalty assessed under this Act, he shall include a statement of the reasons for such action, which shall be published in the Federal Register.

Section 6(f) of the Act (29 U.S.C. § 655(f)) provides:

> (f) Any person who may be adversely affected by a standard issued under this section may at any time prior to the sixtieth day after such standard is promulgated file a petition challenging the validity of such standard with the United States court of appeals for the circuit wherein such person

> resides or has his principal place of business, for a judicial review of such standard. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary. The filing of such petition shall not, unless otherwise ordered by the court, operate as a stay of the standard. The determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole.

ADDENDUM B

LEGISLATIVE HISTORY OF THE STANDARD-SETTING PROVISIONS OF THE OCCUPATIONAL SAFETY AND HEALTH ACT

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ADDENDUM B

LEGISLATIVE HISTORY OF THE STANDARD-SETTING PROVISIONS OF THE OCCUPATIONAL SAFETY AND HEALTH ACT

INTRODUCTION

The Occupational Safety and Health Act was passed in late 1970 after what was characterized as "the most bitter labor-management fight in years." Leg. Hist. 193. The debate in Congress focused, not on the need for legislation providing for occupational safety and health standards, but rather on who (or what body) would promulgate them, and under what criteria they would be developed and reviewed by the courts.

"The shared objective" of the two opposing camps was "to reduce the number and severity of work-related injuries and illnesses which, in spite of current efforts, continue at high levels, and . . . cause human misfortune and economic waste." Leg. Hist. 297 (remarks of Rep. Steiger).

Although both safety and health hazards figured significantly in the congressional debate, occupational health was of particular concern. Congress recognized that the number of toxic chemicals and harmful physical agents in the workplace is increasing,[1] and that the resulting health hazards pose regulatory problems "often different from those involved in occupational safety," since they necessitate "exploring ways to discover latent diseases, establishing causal connections between diseases and work in

[1] *See* Leg. Hist. 142 (Senate Report); Leg. Hist. 845-46 (House Report).

environmental conditions, and conducting research relating to health problems."[2]

In spite of the general agreement that legislation was needed, and that the more subtle problems of occupational health should be considered, Congress was sharply and nearly evenly divided over the means to achieve its "shared objective." The congressional debate focused on three key issues:

(1) who (or what body) would promulgate standards and adjudicate violations;

(2) what criteria and considerations would govern standard-setting; and

(3) what evidentiary record would be required and what test for judicial review would apply.

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[2] S. 2788 § 2(b)(5), Leg. Hist. 33; S. 4404 § 2(b)(6), Leg. Hist. 75; H.R. 13373 § 2(b)(5), Leg. Hist. 681; H.R. 16785 § 2(b)(4), Leg. Hist. 723; H.R. 19200 § 2(b)(6), Leg. Hist. 765.

Thus, *every* occupational safety and health bill contained in the Senate Committee Print of the legislative history of the Act included among its purposes to provide for research in the field of occupational safety and health, and directed the Department of Health, Education and Welfare to conduct research, and specifically authorized the Secretary of Labor to contract for research or other studies. S. 2193 (as introduced) §§ 2(b)(3), 15, Leg. Hist. 2, 23-24; S. 2788 §§ 2(b)(4), 17, Leg. Hist. 33, 63-65; S. 4404 §§ 2(b)(5), 23, Leg. Hist. 75, 126-28; S. 2193 (as reported) §§ 2(b)(2), 18, 19, Leg. Hist. 234, 274-82; S. 2193 (as passed by Senate) §§ 2(b)(2), 19, 20, Leg. Hist. 530, 574-82; H.R. 843 §§ 2(b)(3), 15, Leg. Hist. 600, 621-23; H.R. 3809 §§ 2(b)(3), 15, Leg. Hist. 630, 651-52; H.R. 4294 §§ 2(b)(3), 15, Leg. Hist. 661, 672-75; H.R. 13373 §§ 2(b)(4), 17, Leg. Hist. 681, 711-13; H.R. 16785 (as introduced) §§ 2(b)(3), 19, Leg. Hist. 722-23, 753-57; H.R. 19200 §§ 2(b)(5), 23, Leg. Hist. 765, 816-18; H.R. 16785 (as reported) §§ 2(b)(3), 19, Leg. Hist. 832, 841-842; H.R. 16785 (as passed by House) §§ 2(b)(5), 23, Leg. Hist. 1092, 1107-08.

One faction in both houses supported the Daniels bill (H.R. 16785) and a closely similar bill (S. 2193) sponsored by Senator Williams. These bills provided for standard-setting by the Secretary of Labor under informal rulemaking procedures with judicial review based on the "arbitrary and capricious" test. They also vested in the Secretary of Labor the responsibilities of investigating, prosecuting, and adjudicating violations of standards.[3]

The Daniels and Williams bills provoked vigorous opposition in both houses and by the Administration. Opponents charged that these proposals created "a great potential for abuse" and might result in "frivolous disruptions of industrial production under arbitrary and arrogant administration by the U.S. Department of Labor." Leg. Hist. 420, 1080. These concerns arose both because the Daniels and Williams bills prescribed "unfair regulatory procedures" which "permit adoption of administrative regulations based on 'views and arguments' rather than solely on probative evidence," and because they would permit employer interests to be largely ignored by the Secretary of Labor, "who has traditionally been the voice of labor in the administration." Leg. Hist. 474-75, 884, 982, 1014.

Opponents of the Daniels and Williams bills supported far different proposals—initially an Administration bill (S. 2788, H.R. 13373) sponsored by Senator Javits, and later the Administration-backed Steiger-Sikes Substitute (H.R. 19200, S. 4404). The latter bill: (i) placed standard-setting authority in

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[3] *See* H.R. 16785 (as introduced) §§ 7(a)(2), 9-11, Leg. Hist. 729-30, 735-42; S. 2193 (as introduced) §§ 6, 8-10, Leg. Hist. 240-46, 249-61.

an independent board; (ii) provided formal rulemaking procedures with judicial review based on the "substantial evidence" test; and (iii) effected a "separation of powers" by creating an independent body to adjudicate enforcement cases.[4]

What ultimately emerged was a compromise between the Daniels-Williams proposals and the Administration approach. In return for leaving standard-setting authority in the Labor Department, Administration forces obtained: (i) substantive and evidentiary limitations on the Secretary's standard-setting authority; (ii) inclusion of the "substantial evidence" review standard; and (iii) an independent board (the Occupational Safety and Health Review Commission) to adjudicate enforcement cases. This Addendum treats the legislative history of these developments in chronological order.

A. Consideration by the House Committee on Education and Labor

The first major confrontation between the two opposing camps took place in the House Committee on Education and Labor. By a narrow margin (19-15), the House Committee voted down the Administration-backed Steiger-Sikes Substitute (H.R. 19200), which had been offered in committee by Representatives Steiger (R.-Wisc.) and Hathaway (D.-Me.) as a "bipartisan compromise" between the initial Administration bill (H.R. 13373) and the Daniels bill (H.R. 16785). Leg. Hist. 988, 1057. Instead, the Committee favorably reported the Daniels bill with amendments which, with one exception, made

[4] *See* H.R. 19200 §§ 6, 8-11, Leg. Hist. 770-76, 779-96.

no significant change in the major provisions of the bill as introduced.[5]

The exception was the addition of a provision recognizing the somewhat different problems presented by occupational health hazards. The House Report observed that, unlike safety hazards, which "are often immediately apparent" and where it is usually possible to identify "a clear cause and effect" relationship, "[d]iseases resulting from occupational health hazards may not become known until years after continuous exposure have elapsed." This detection problem arises because of the "long latent period[s]" between exposure to a hazard and the onset of disease, or because chronic exposure may be required before health effects appear. Leg. Hist. 853-54.

For these reasons, the Committee elaborated the following special standard-setting criteria, which were to apply specifically to "occupational health standards" (Leg. Hist. 848):

> The Secretary, in promulgating standards under this subsection, shall set the standard which most adequately assures, on the basis of the best available professional evidence, that no employee will suffer any impairment of health, or functional capacity, or diminished life expectancy even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.[6]

[5] *See* H.R. 16785 (as reported) §§ 7, 9-11, Leg. Hist. 934, 940-43, 949-55.

[6] H.R. 16785 (as reported) § 7(a)(4), Leg. Hist. 943.

Although this provision was considered necessary to account for the different problems presented by occupational health hazards,[7] the Committee did not indicate that it wanted stricter standards for health (as opposed to safety) hazards. To the contrary, the Committee stressed that it did not intend to provide absolute health protection. Thus, the Committee made clear that "while [health standards] will reflect" NIOSH criteria "describing medically acceptable tolerance levels of exposure to harmful substances or conditions over a period of time, . . . they may be modified by practical considerations such as feasibility, means of implementation, and the like." Leg. Hist. 857-58.

With this addition, the Daniels bill was reported by the House Committee, but not without vigorous dissents from supporters of the Administration approach, who complained bitterly about the majority's refusal to entertain even the slightest compromise. The minority considered the Daniels bill "unacceptable" because it "ignore[d] the element of fairness to those required to comply with the Act." Leg. Hist. 877. Citing the "substantial financial impact" the Act would have on employers, they denounced the bill for allowing standards to be based on " 'views and arguments' rather than probative

[7] As explained by the House Committee, this provision would require the Secretary, in formulating "occupational health standards," to act "on the basis of the best available evidence," so as not to "be paralyzed by debate surrounding diverse medical opinions." Leg. Hist. 848.

evidence." Leg. Hist. 884.[8] By contrast, they stressed the need for standards to be established by an independent board "based on substantial evidence" and accordingly promised to offer the Steiger-Sikes bill as a substitute for the Daniels bill on the House floor. Leg. Hist. 881-82.

Before the full House could consider the Committee bill, however, the Senate Labor and Public Welfare Committee began its own review of a closely-similar bill introduced by Senator Williams. It is to this Senate Committee consideration that we now turn.

B. Consideration by the Senate Committee on Labor and Public Welfare

Like its House counterpart, the Senate Labor and Public Welfare Committee voted to reject the Administration-backed Steiger-Sikes Substitute (S. 4404 in the Senate), and to report favorably an amended version of the bill previously introduced by Senator Williams (S. 2193, Leg. Hist. 1). The Senate Committee's bill was similar in most major respects to the Daniels bill reported in the House,[9] and was criticized by the minority for much the same reasons as had been advanced in the House. Leg. Hist. 200-03. Although the Senate Committee had for the most part developed its bill independently, it specifically chose to follow the House Committee's approach of providing special criteria for setting health standards. Leg. Hist. 242.

[8] The minority charged that there was "[n]o reason" for "this deviation from regular and fair procedures," and that under the Committee bill, "[t]he requirements that administrative decisions be based on facts and sound reasons mean little." Leg. Hist. 884.

[9] *See* S. 2193 (as reported) §§ 6, 8-10, Leg. Hist. 240-46, 249-61.

But unlike their House counterparts, the Senate Committee's minority members were able to secure a series of compromises relaxing several of the more objectionable features of the Williams bill. *See* Leg. Hist. 196-98. Two of these amendments, which affected the standard-setting criteria incorporated from the House Committee's bill, were designed to assure that standards would be "reasonable" and "practical," and that the Secretary would, in every case, base his standards on all available scientific evidence.

1. The Javits "feasibility" amendment

The first minority amendment was suggested by Senator Javits, the ranking minority member of the Senate Committee, and sponsor of the initial Administration bill (S. 2788). To allay the concerns of those, including Senator Javits, who feared that the Daniels bill "might be interpreted to require absolute health and safety protection in all cases, regardless of feasibility" (Leg. Hist. 197), the Senate Committee amended the Daniels criteria—to read "the standard which most adequately *and feasibly* assures, . . ."[10]—thereby signifying the Committee's intent that "standards promulgated under section 6(b) shall represent feasible requirements." Leg. Hist. 147.

By persuading the Committee to adopt his "feasibility" amendment (*see* Leg. Hist. 418), Senator Javits succeeded in reconciling the Williams bill with the Administration view on this issue. The Administration's initial proposal, authored by Senator Javits himself (Leg. Hist. 316), had expressly contemplated that all health and safety standards be

[10] S. 2193 (as reported) § 6(b)(5), Leg. Hist. 242 (emphasis added).

"feasible," meaning not only that standards be "technologically feasible" but also "reasonable" and "practical" as well.

Specifically, Senator Javits' bill (S. 2788) would have required a National Occupational Safety and Health Board to submit any proposals for permanent standards "to the appropriate national standards-producing organization" for a report on "the *technical feasibility, reasonableness* and *practicality* of such standard."[11] Senator Javits described this as "a report on the feasibility of the proposed standards."[12] This "feasibility report" was to be considered by the Board (along with other record evidence) in formulating its standards. Moreover, the Secretary of Labor or the Secretary of Health, Education and Welfare was permitted to force a reconsideration by filing a "written objection" that the standard chosen "is not feasible."[13]

Accordingly, although the Senate Committee refused to adopt the Administration proposal for standard-setting by an independent board, it nevertheless accepted Senator Javits' compromise requiring that standards set by the Secretary of Labor be "feasible" in the sense of being reasonable and practical. This was the meaning of "feasible" as understood, not only by Senator Javits, but by other members of the Senate Committee as well. *See* p. 17b, *infra*.

[11] S. 2788 § 4(c), Leg. Hist. 38-39 (emphasis added).
[12] 115 Cong. Rec. 22517 (August 6, 1969).
[13] S. 2788 § 4(c)(2), (3), Leg. Hist. 39-40.

2. The requirement that standards be based on "the best" and "latest available" scientific evidence, "research, demonstrations, [and] experiments," plus "experience gained under this and other health and safety laws"

Apart from the "feasibility" amendment, the Senate Committee engrafted a series of additional requirements onto the Daniels standard-setting criteria. As redrafted by the Senate Committee, Section 6(b)(5) read as follows:

> The Secretary, in promulgating standards under this subsection, shall set the standard which most adequately *and feasibly* assures, on the basis of the best available [professional] evidence, that no employee will suffer any impairment of health or functional capacity, or diminished life expectancy even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. *Development of such standards shall be based on research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws.*[14]

These additional provisions were designed to require the Secretary to act, not on the basis of "views" or "arguments" (as permitted under the

[14] S. 2193 (as reported) § 6(b)(5), Leg. Hist. 242 (new material in italics, deleted material in brackets).

House Committee's criteria, *see* p. 6b-7b, *supra*), but rather on "the best available" scientific and factual evidence. By providing that standards "shall be based on" scientific data—*i.e.*, "research, demonstrations, experiments, and . . . other information"—the Committee underscored its intent that the Secretary develop scientifically-based, factually supportable standards.[15]

Moreover, the Senate Committee's amendments prohibited the Secretary from ignoring advances in the state of the art for regulating health or safety hazards, and required instead that he consider "the latest available" scientific knowledge "in the field," particularly where reflected in "experience under this and other health and safety laws."

C. Consideration by the Full Senate

Notwithstanding their success in committee, Senate supporters of the Administration view, led by Senator Dominick, continued to urge passage of the Steiger-Sikes Substitute during the Senate debates.

[15] The obligation imposed on the Secretary to act on the basis of "research, demonstrations, [and] experiments" was complemented by the "research" provisions already in the Committee bill. Section 19 of the bill created a new National Institute of Occupational Safety and Health ("NIOSH") to conduct research and experimental programs. Leg. Hist. 279-82. Section 18(b) of the bill specifically authorized the Secretary to enter into contracts with public or private organizations "for the purpose of conducting studies related to the establishing and applying of occupational safety and health standards. Leg. Hist. 277. Apparently recognizing that research activities contracted for by the Secretary would often be different from and supplementary to those of NIOSH, Section 18(b) directed the Secretary to cooperate with the Department of Health, Education and Welfare (of which NIOSH is a part) "to avoid any duplication" of research efforts. *Id.*

As summarized below, their efforts resulted in further limitations on the Secretary's power, including: (i) a split of authority between the Secretary of Labor and an independent Review Commission; and (ii) additional modifications in the standard-setting criteria of Section 6(b)(5).

1. Split of authority between the Secretary of Labor and an independent Review Commission.

During the Senate floor debates, supporters of the Administration approach continued to express concern about the "unfair regulatory procedures" (Leg. Hist. 298) of the Committee bill, and urged the Senate to pass "a balanced bill," because "[w]e cannot just have a bill set up for the employee and not worry about the employer, because someone has to provide the job." Leg. Hist. 320. One of the "unfair regulatory procedures" they cited was an undesirable concentration of power in the Secretary of Labor. Leg. Hist. 298. Senate supporters of the Administration approach also charged (i) that the informal rulemaking procedures of the reported bill were inadequate because they did not involve the making of a "formal record," so that, as a result, "standards could not be based on substantial evidence of record" (Leg. Hist. 298-99); and (ii) that the "arbitrary and capricious" standard of review prescribed in the Committee bill seriously undermined the right to a judicial remedy because "it will be very, very strange if they can ever win a case." Leg. Hist. 343-44.

The Senate ultimately adopted a compromise between the Committee bill and the Steiger-Sikes

Substitute. Although a motion to table the Steiger-Sikes measure was passed by a narrow margin (41 to 39), the Senate approved another pending amendment—a compromise sponsored by Senator Javits—which incorporated into the Committee bill the Steiger-Sikes provision for an independent body to adjudicate enforcement cases. Leg. Hist. 445, 478.[16] By achieving a "separation of powers" in the overall administration of the Act, this amendment eliminated one of the major reasons for concern about the issuance of arbitrary regulations under the Williams Bill.[17]

2. Further amendments to the standard-setting provisions on the Senate floor

Not satisfied with the Senate Committee amendments to the standard-setting provisions (*see* pp. 7b-11b, *supra*), proponents of the Steiger-Sikes bill continued to press for further amendments to the Committee bill on the Senate floor. Among the most significant of these floor amendments was a clarification of the first sentence of Section 6(b)(5).

During the floor debates, Senators Dominick and Saxbe, among others, expressed reservations that Section 6(b)(5)—even after the compromise "feasibility" amendment and inclusion of a require-

[16] Senator Javits' compromise amendment had previously failed in committee by a vote of 10 to 7. Leg. Hist. 194-95.

[17] However important this compromise may have been, other concerns remained unsatisfied (*see* p.12b, *supra*) and as a result the Steiger-Sikes proponents later succeeded in persuading the House to pass their Substitute. *See* p. 18b, *infra*. Consequently, the House-Senate Conference Committee was faced with the need to make still further compromises. *See* pp. 19b-21b, *infra*.

ment that standards be based on scientific evidence—was still "inherently confusing and unrealistic." Leg. Hist. 367.

First, the apparent prohibition against "any" impairment of health and "any" dimunition of life expectancy was said to be impractical since some risk was thought to be the handmaiden of all employment. Leg. Hist. 337. Senate Saxbe stressed the inherent trade-off between employment and health since "any type of exposure is going to affect" functional capacity and life expectancy. Leg. Hist. 338. He illustrated this point as follows:

> One example is working in a paint shop or working in an automobile line, a final assembly line, or on a paint line .... [S]ubstantial skill is required to be an automobile painter, which means that the person who acquires this skill already has a substantial buildup of inhaled paint particles before he achieves the skill required to hold a steady job.

Leg. Hist. 338.

Citing similar examples of a bus or street car driver constantly exposed to risks of air pollution and traffic accidents (Leg. Hist. 423, 481), Senator Dominick sought to avoid any implication that standards "must assure that there will not be any risk at all." Leg. Hist. at 481. For "there is no way a criteria [sic] can be established so that an employee would not be faced with some risks for the period of his working life." Leg. Hist. 481-82.

A closely-related concern was that the purpose of Senator Javits' "feasibility" amendment had not

been given full effect in the Committee's bill. As Senator Dominick explained, the first sentence of Section 6(b)(5)

> could be read to require the Secretary to ban all occupations in which there remains *some* risk of injury, impaired health, or [diminished] life expectancy. In the case of all occupations, it will be impossible to eliminate all risks to safety and health. Thus, the present criteria could, if literally applied, close every business in this nation. In addition, in many cases, the standard which most "adequately" and "feasibly" assures the elimination of the danger would be the prohibition of the occupation itself.

Leg. Hist. 367 (emphasis in original). *See also* Leg. Hist. 480-81.

In Senator Dominick's view, although it was appropriate to recognize that health hazards may pose new and different problems because of long latency periods or the effects of cumulative exposures, the degree of protection provided to workers should be determined based on the same overriding regulatory considerations applicable to safety hazards. In either case, the fundamental question is how much protection to provide (or how much risk to eliminate), for, as Senator Dominick stressed, "[i]t is unrealistic to attempt, as this section apparently does, to establish a utopia free from hazards. Absolute safety is an impossibility . . . ." Leg. Hist. 480.

Consequently, Senator Dominick concluded that it would be better to drop the first sentence of Section 6(b)(5) altogether and assume that the Secretary

would take the special problems of latency periods and cumulative exposures into account in regulating health hazards. Leg. Hist. 480. But after offering an amendment to that effect, Senator Dominick moved that it "be temporarily laid aside" in light of "modifications" that he was discussing with Senators Williams and Javits. Leg. Hist. 482.

Senator Dominick then introduced a "substitute amendment" which he had "worked . . . out" with Senators Williams and Javits and which he believed was "agreeable to all." Leg. Hist. 502. This substitute amendment revised the first sentence of Section 6(b)(5) as follows:

> The Secretary, in promulgating standards *dealing with toxic materials or harmful physical agents* under this subsection, shall set the standard which most adequately [and feasibly] assures, *to the extent feasible*, on the basis of the best available evidence, that no employee will suffer *material* [any] impairment of health or functional capacity [or diminished life expectancy] even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.

Leg. Hist. 502 (new material in italics, deleted material in brackets).

This consensus amendment, which was adopted without objection, accomplished three things.

First, it clarified that the first sentence of Section 6(b)(5) was addressed to "toxic materials or harmful physical agents," thereby making explicit

what the House Committee had originally intended when it first drafted the provision—*i.e.*, that it applied only to "occupational health standards." *See* pp. 5b-6b, *supra*.[18]

Second, the amendment developed by Senators Dominick, Williams and Javits gave full effect to the intent of Senator Javits' "feasibility" amendment by rewording the provision to make feasibility a clear limitation. As explained by Senator Dominick:

> What we were trying to do in the bill—unfortunately, we did not have the proper wording or the proper drafting—was to say that when we are dealing with toxic agents or physical agents, we ought to take such steps as are feasible and practical to provide an atmosphere within which a person's health or safety would not be affected.

Leg. Hist. 502. The committee chairman, Senator Yarborough, explained that with this amendment, "[a]ll the bill requires is reasonable safety devices" and "reasonable safety standards." Leg. Hist. 511, 512.

Third, Senator Dominick's consensus amendment substituted the word "material" for the word "any." This change further underscored Senator Javits'

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[18] Senator Dominick's amendment also left no doubt that the second and third sentences of Section 6(b)(5) apply to *all* permanent standards, including safety standards. Specifically, the introductory phrase of the second sentence was changed (*see* p. 10b, *supra*, for previous text) to refer to "*standards under this subsection*" —*i.e.*, subsection (b) of Section 6, providing for the development of both health standards *and safety* standards. Leg. Hist. 502.

feasibility amendment by limiting the Secretary's standard-setting power to "material impairment" of health. From the legislative debate summarized above, it is apparent that this change addressed the concerns expressed by Senators Dominick and Saxbe that the expression "any impairment" would have allowed the Secretary to regulate immaterial or inconsequential "risks." *See* pp. 14b-15b, *supra*.

After this and other amendments not directly relevant here, the Senate passed the Committee bill on November 17, 1970. Leg. Hist. 528.

D. House Rejection of the Daniels Bill and Passage of the Steiger-Sikes Substitute

Despite these Senate amendments, supporters of the Administration view in the House continued to press for passage of the Steiger-Sikes Substitute when the full House took up the Daniels bill on November 23, 1970. Support for the Administration view proved even stronger in the House than in the Senate—so strong, in fact, that it soon became clear that the real choice in the House was between the Steiger-Sikes Substitute and no legislation at all. Leg. Hist. 1089.[19] When the issue came to a vote on November 24, 1970, the Steiger-Sikes Substitute prevailed 220 to 172. Leg. Hist. 1112.

[19] The vigorous opposition to the Daniels bill (as reported by the House Committee) was based on objections previously discussed at pp. 3b, 6b-7b, 12b *supra*. *E.g.*, Leg. Hist. 1013, 1014 (Rep. Scherle), 1016 (Rep. Erlenborn), 1053, 1062 (Rep. Sikes).

E. Further Compromises in the House-Senate Conference Committee.

House passage of the Steiger-Sikes Substitute set the stage for still further compromises. To be sure, both houses, as a result of Senator Javits' amendment on the Senate floor, had passed the Steiger-Sikes proposal for an independent Review Commission to adjudicate enforcement cases. Moreover, House proponents of the Steiger-Sikes Substitute were apparently satisfied with the standard-setting requirements in Section 6(b)(5) of the Senate bill, including the evidentiary requirements of the second and third sentences, Senator Javits' "feasibility" amendment, and Senator Dominick's clarification of the first sentence of Section 6(b)(5).[20] Nevertheless,

[20] The House bill contained no standard-setting criteria for "toxic materials or harmful physical agents" corresponding to the first sentence of Section 6(b)(5) of the Senate bill, but instead directed that standards "carry out the purposes of this Act." Leg. Hist. 1121. In effect, the House had adopted Senator Dominick's initial approach of assuming, without specific statutory direction, that the standard-setter would take the special regulatory issues posed by health hazards into account in developing standards which meet the overall goals of the Act. *See* pp. 15b-16b, *supra*. Since Senator Dominick's substitute amendment accomplished the same purpose, there was no serious difference between the House and Senate provisions.

Nonetheless, the House Conferees won approval for a provision allowing individual employers to obtain temporary variances from standards because of their inability to obtain the personnel, materials or equipment needed for compliance. Leg. Hist. 1188.

two key issues remained: (i) who (or what body) would formulate occupational safety and health standards; and (ii) what would be the test for judicial review of such standards.

Because both houses had acted so late in the legislative session (November 17 in the Senate and November 24 in the House), the Conference Committee had little time to resolve these remaining differences before adjournment. Whether because of the impending adjournment or for other reasons, the Committee quickly reached an acceptable compromise. The anti-Administration forces prevailed on who (the Secretary of Labor) would be authorized to set occupational health and safety standards, and Administration forces prevailed on whether the stricter test ("substantial evidence") would govern judicial review under the Act.[21]

[21] There were, of course, other points on which a compromise was reached. For example, the Conference Committee adopted the House bill's statement of the Act's purposes, which was "more detailed" (Leg. Hist. 1185), and which emphasized more strongly the role of research in proper implementation of the Act. These House provisions (now Sections 2(b)(5) & (6) of the Act) provide expressly that the Act's overall purpose of "safe and healthful workplaces so far as possible" shall be achieved, *inter alia*, "by providing for research in the field of occupational safety and health" and "by exploring ways to discover latent diseases, establishing causal connections between diseases and work in environmental conditions and conducting other research relating to health problems." Leg. Hist. 1155. The Committee also adopted the broader House provision (Section 20(c)) authorizing the Secretary to contract for studies relating to all of his responsibilities under the Act, rather than only with respect to his standard-setting responsibilities. *See* Leg. Hist. 1176.

It was the Senate's acquiescence in the more rigorous "substantial evidence" test (Section 6(f)) that led proponents of the Steiger-Sikes Substitute to recommend passage of the Conference bill. Thus, Congressman Steiger, the floor leader for the Steiger-Sikes Substitute, urged his colleagues to approve the Conference Report, but only because the "substantial evidence" test would provide adequate protection against fears that employer interests might be ignored by the Secretary:

> The Secretary's standard will only be sustained by the court if it is supported by "substantial evidence on the record considered as a whole." Thus, the Secretary must have a record on which to base his findings and to serve as the basis for judicial review. The act does not provide for an independent board for standard-setting as did the House bill. However, court review based upon substantial evidence provides a sufficient element of fairness to satisfy me that the conference report should be adopted.

Leg. Hist. 1218.

After Senate approval on December 16, the Conference Report, with Representative Steiger's support, passed the House by a vote of 308 to 60 on December 17, 1970. Leg. Hist. 1225. Twelve days later, on December 29, 1970, the Conference Bill became law. Leg. Hist. 1229.

ADDENDUM C

DECISIONS INVOLVING HEALTH RISKS: THE EXPERIENCE OF OSHA AND OTHER HEALTH AND SAFETY AGENCIES

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ADDENDUM C

DECISIONS INVOLVING HEALTH RISKS: THE EXPERIENCE OF OSHA AND OTHER HEALTH AND SAFETY AGENCIES

In an effort to undercut the decision below, counsel for OSHA and others supporting reversal attempt to leave the erroneous impression that techniques for evaluating health risks are too imprecise to be helpful, and that they are of no use in deciding how health protection resources should be allocated. OSHA Br. 65-70. Likewise, OSHA wrongly implies that it would face regulatory paralysis or inordinate delays if it considered or used such techniques in decision-making.

But, as we show in this Addendum,[1] qualitative and quantitative techniques for assessing health risks and for estimating the likely benefits of regulation have been common since the 1960's (*see* nn. 25 & 26 *infra*).[2] Indeed, virtually every other federal

[1] In contrast to the briefs supporting reversal, which rely heavily on selective citations from the general literature, this Addendum will rely on the record in this case, and the actions of OSHA and other federal agencies taken after full, public rulemaking proceedings. Respondents also draw from the rulemaking record on OSHA's Proposed Rule for the *Identification, Classification, and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk*, 42 Fed. Reg. 54148 (October 4, 1977). References to testimony in that proceeding will be identified as part of the "OSHA Cancer Policy Record," and are available for inspection at OSHA's Technical Data Center in Docket H-90.

[2] Indeed, even techniques for comparing costs and benefits —although not an issue in this case—have long been used by federal agencies. For example, the Army Corps of Engineers has used such cost-benefit analyses for decades in carrying out its mandate under the Flood Control Act of 1936.

health and safety agency uses such techniques, and even OSHA has employed them on occasion. Moreover, various interagency groups within the federal government have endorsed their use, especially for regulating carcinogens where evaluation of relative risks both sharpens decision-making and helps to assure that resources are allocated in a rational and cost-effective manner.

A. Decision-Making When Uncertain Health Risks Are Presented

Regulatory decisions involving health hazards, including (but not limited to) carcinogens, must often be made in the absence of definitive information. Whenever this is the case, decision-makers must either (i) extrapolate from the best available scientific information to estimate what their actions will accomplish; or (ii) ignore the available factual data and make a decision without any estimate of the degree of risk likely to be prevented.

One advantage of the former course is that it narrows the areas of scientific uncertainty and focuses debate on the appropriateness of any assumptions required to fill gaps in the existing data. The disadvantages of making no estimate at all are many and obvious,[3] but one of the most serious is that proceeding without even a rough approximation of risk tacitly equates and treats identically all hazards

[3] *See* Main Brief 16-20, 65-68, 72-78. As the National Academy of Sciences ("NAS") has concluded, decisionmaking based on the best available information concerning the magnitude of the health risk in question "represent[s] a significant advance" over the "intuitive, ad hoc, unsystematic, and often frantic methods now used." NAS, DECISION MAKING FOR REGULATING CHEMICALS IN THE ENVIRONMENT 45 (1975).

about which less than perfect information exists. Unless health protection resources are assumed to be limitless, making any decision without at least some estimate of the degree of risk involved will inevitably lead to misallocation and waste of finite health protection resources.

This problem is especially severe in the case of carcinogens, where the controversy has been brewing for years over whether there is or is not an absolutely safe level for exposure to cancer-causing substances. It makes no sense to treat all of the approximately 2000 potential occupational carcinogens the same[4] when carcinogenic potency can vary among substances by a factor of as much as one million.[5] Moreover, these differences in potency are only one factor that affect the degree of risk; others include variations in exposure patterns and the size of the population involved.[6] The practical importance of

[4] *See* Main Brief p. 4 n.5.

[5] *Id.* 72 n.105 *See also* (from the OSHA Cancer Policy Record) Testimony of Dr. Arthur Upton (Director of the National Cancer Institute), Tr. 319; Statement of Dr. Roy Albert (Chairman of EPA's Carcinogen Assessment Group), Exh. 219-1-A at 10; Testimony of Dr. Richard Peto (Oxford University) Tr. 2581; Statement of Dr. Joyce McCann (University of California at Berkeley) Exh. 183-5 at 18.

[6] HEW's departmental critique of the benzene standard recognized these differences. Main Brief p.73 n.107 *See also* Testimony of Grover C. Wrenn (then OSHA's Director of Health Standards Programs), OSHA Cancer Policy Record, Tr. 239-41.

these differences for regulatory decision-making is seen by comparing the benzene standard with previous OSHA standards for more potent carcinogens such as asbestos and vinyl chloride.[7]

OSHA dwells on the uncertainties of risk estimation, such as problems of extrapolating from animal studies to man, determining the levels of exposure involved in human epidemiologic studies, and selecting a dose-response function.[8] The scientific community, while recognizing that these uncertainties prevent highly accurate estimates, has nevertheless repeatedly endorsed the use of risk assessment techniques.[9] The National Research Council, for example, has concluded that even when the underlying evidence of carcinogenicity consists of animal bioassays, "a 'most probable risk' can be estimated by appropriate statistical treatment" to obtain "an upper limit

[7] For example, while the benzene standard may, based on EPA estimates, prevent one case of leukemia every 15 to 38 years, it has been estimated that OSHA's asbestos standard will prevent *1,596 deaths per year*. *See* references cited in Joint Memorandum in Opposition to Certiorari for Respondents API, *et al.*, Nos. 78-911 & 78-1036, filed January 26, 1979, at 20 n.44, 21-22 nn.48, 49.

[8] OSHA Br. 60-70. As discussed in the body of this Brief (p. 79), these do not apply in the case of benzene.

[9] Indeed, all of the literature sources cited by the Natural Resources Defense Council which discuss risk assessment actually endorse its use. *See* Crump, *et al.*, *Fundamental Carcinogenic Processes and Their Implicatons for Low Dose Risk Assessment*, 36 CANCER RESEARCH 2793 (1976) ("[S]ome [carcinogens] may be avoided only at great expense or alternative risk, in which case 'risk versus benefit' must be evaluated."); Mantel & Schneiderman, *Estimating Safe Levels, a Hazardous Undertaking*, 35 CANCER RESEARCH, 1379, 1380 (1975) ([C]ost benefit consideration must enter into adjudication of any safety considerations."); Cornfield, *Carcinogenic Risk Assessment*, 198 SCIENCE 693 (1977) ("Risk assessment is . . . an essential component of regulatory decisions."). *See also* n.3 at 2c, *supra*, nn.10, 18, *infra*.

of the risk to human populations."[10] The heads of other scientific groups, such as the National Institute of Environmental Health Sciences ("NIEHS"), have reached the same conclusion.[11]

Furthermore, risk estimation has recently been endorsed by various science-oriented segments of the executive and legislative branches of the federal government. For example, the Interagency Regulatory Liaison Group, which was established in September 1977 to coordinate regulatory activities among agencies concerned with protection of the public health and the environment,[12] recently issued a Report[13] reviewing the scientific concepts and methods for quantitatively assessing human cancer risks. This Report observed that "[d]espite the uncer-

[10] NATIONAL RESEARCH COUNCIL, DRINKING WATER AND HEALTH, 27-28, 56 (1977). *See also* NATIONAL ACADEMY OF SCIENCES, PRINCIPLES FOR EVALUATING CHEMICALS IN THE ENVIRONMENT 88 (1975) (Concluding that "[t]he statistical problems of extrapolation from experimental dose levels to very low levels . . . can be handled if care is taken in the design and analysis of the experiments and the interpretation of the results.").

[11] Testimony of Dr. David Rall (Director, NIEHS), OSHA Cancer Policy Record, Tr. 449 (Despite the uncertainties attending risk assessments, "we have got to use them."); Testimony of Dr. David Hoel (Biometry Branch Chief, NIEHS), OSHA Cancer Policy Record, Exh. 183-23 at 1-2 ("[T]here is clearly a need to assess quantitatively the risk to man at low exposure levels in order to have rational standard setting and methodology.").

[12] Initially, the IRLG was composed of the Consumer Product Safety Commission, the Environmental Protection Agency, the Food and Drug Administration and OSHA. In January 1979, the Food Safety and Quality Service of the Department of Agriculture joined the IRLG as its fifth member.

[13] IRLG, *Scientific Basis for Identifying Potential Carcinogens and Estimating Their Risks*, 44 Fed. Reg. 39858, 39871-76 (July 6, 1979).

tainties" involved, "risk estimates can be and are being made, not only by some regulatory agencies but by other scientific bodies," and concluded that "preliminary observations suggest that current methodologies may not lead to serious error."[14]

The importance of risk estimation in regulatory decision-making has been emphasized even more pointedly by economic and scientific advisory panels in the Executive Office of the President. Thus, in a staff paper prepared by the President's Office of Science and Technology Policy, the President's science advisors concluded that the "determination that a particular chemical might be carcinogenic in humans is only the first step" in regulatory decision-making.[15] Additional data "must be sought and some quantitative estimate of overall risk (and uncertainty) made if regulatory agencies are to act prudently in establishing controls over the use of potential carcinogens."[16]

Moreover, in a separate analysis presented to OSHA during its recent rulemaking proceedings on its proposed Cancer Policy (*see* n.1 at 1c, *supra*), the President's Council on Wage and Price Stability strongly urged that quantitative risk estimation is

[14] *Id.* 39871. The IRLG made this observation regarding extrapolation from animal models to humans and went on to note that extrapolation of risk from one observed human population to other human exposures—the situation presented in the case of benzene—"carries less uncertainty than extrapolations from animals to humans." *Id.*

[15] OFFICE OF SCIENCE AND TECHNOLOGY POLICY, IDENTIFICATION, CHARACTERIZATION, AND CONTROL OF POTENTIAL HUMAN CARCINOGENS: A FRAMEWORK FOR FEDERAL DECISION-MAKING 14 (February 1, 1979).

[16] *Id.*

essential if OSHA is to "lay a solid foundation for the most rational regulatory decisions possible."[17]

In short, the recommendations of the President's Council and the Department of Health, Education and Welfare in connection with the benzene standard reflect a large and rapidly expanding body of scientific and governmental opinion supporting the use of risk assessment techniques in regulatory decision-making. The scientific community itself has repeatedly endorsed efforts to obtain better information concerning relative cancer risks. The purpose of the process that they recommend is not to substitute mathematical cost-benefit analyses for regulatory judgments. Instead, information concerning the health benefits and costs of regulatory options is desirable—even imperative—to organize and synthesize the available data and to provide a framework for rational decisionmaking.[18]

[17] Comments of the Council on Wage and Price Stability, OSHA Cancer Policy Record, Exh. 253 at 20. The President's Council observed that "[c]ancer risk quantification" "affords some measure, however imprecise, of the magnitude of the cancer risk, which can be an important factor in determining how to regulate a substance or what priority to assign its regulation." *Id.* The Council cautioned that in the absence of information on the magnitude of the hazard involved, "society cannot hope to allocate its scarce resources rationally to all of the ills which it faces." *Id.*

[18] As the National Academy of Sciences ("NAS") has observed:

> There is no scientific formula for making decisions .... There is no satisfactory way to summarize all the costs or benefits of regulatory options in dollars or other terms which can mathematically be added, subtracted, or compared. In short, there is no substitute for an experienced decision maker exercising

(footnote continued on next page)

B. Experience of Other Health and Safety Agencies

Because of the wide and growing acceptance of such techniques in the scientific community, risk assessment has increasingly been used by federal agencies concerned with regulating cancer-causing substances. Indeed, virtually every other federal health agency routinely assesses the degree of risk prevented (*i.e.*, the benefits) of its regulatory decisions regarding carcinogens.

For example, the Environmental Protection Agency ("EPA") routinely conducts risk assessments under an agency-wide policy, adopted in 1976, which requires "that appropriate analyses of the risks and benefits of suspected carcinogenic chemicals [be] performed as part of the regulatory process." 41 Fed. Reg. 21402, 21402-03 (May 25, 1976). The purpose of these analyses is to "formulat[e] judgments concerning the nature and magnitude of the cancer hazard from suspected carcinogens," including an estimate of the "possible impact" of each substance "on the public health at current and anticipated levels of exposure." *Id.* 21404.[19]

(footnote continued from previous page)

> good judgment. However, the techniques developed by decision theory and benefit-cost analysis can provide the decision maker with a useful framework and language for describing and discussing trade-offs, noncommensurability, and uncertainty. They can also help clarify the existence of alternatives, decision points, gaps in information, and value judgments concerning trade-offs.

NATIONAL ACADEMY OF SCIENCES, DECISIONMAKING FOR REGULATING CHEMICALS IN THE ENVIRONMENT 2 (1975) (emphasis added).

[19] To accomplish this goal, EPA has created a special Carcinogen Assessment Group ("CAG") whose charge is to "conduct analyses of data related to risk and make recommendations . . . concerning the risk associated with each suspect carcinogen." *Id.* 21403. It was the CAG which developed EPA's risk estimate for benzene. A. 14-29.

In adopting this policy, EPA rejected any suggestion that these procedures might result in "regulatory paralysis" or that they are too imprecise to be useful. EPA understood that there will often be "uncertainty in the data and extrapolation techniques," but concluded that valuable information can be obtained from risk assessments "based on currently available information." *Id.* 21404-05. Thus, far from "unduly delay[ing] regulatory decisionmaking," EPA found that the use of risk assessments represents

> a significant step toward the objective of achieving real benefits in improved public health while avoiding the burdens of undesirable regulatory action.

Id. 21403. Based on its experience under this policy,[20] EPA has strongly urged OSHA to use risk estimation in its decisionmaking process as well.[21]

Like EPA, the Food and Drug Administration ("FDA") routinely uses risk estimation procedures in

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[20] EPA has completed well over 30 risk assessments under its current policy. *See* Testimony of Roy Albert (Chairman, CAG), OSHA Cancer Policy Record, Tr. 2293. Examples of such risk assessments are contained in Exhs. 219-2, 219-3-A, 291-3-E, 219-4.

[21] *See, e.g.*, the following testimony in the OSHA Cancer Policy Record: Statement of Dr. Roy Albert (Chairman, CAG), Exh. 183-46 at 6 ("[B]ecause carcinogens can vary in potency by as much as a millionfold, OSHA should strongly consider using quantitative risk assessment . . . as a factor in judging feasibility of regulatory control."); Statement of Steven Jellinek, Exh. 183-46 at 5 ("We encourage OSHA to include risk estimation in its regulatory process.").

developing its regulations,[22] and, based on this experience, has urged OSHA to do the same.[23] In fact, FDA has recently proposed to make risk assessment a regular part of its administration of the Delaney Clause.[24]

Similarly, the Consumer Product Safety Commission ("CPSC") performs risk assessments as a routine matter in regulating products that may present unreasonable risks of injury to consumers. For example, CPSC developed quantitative risk estimates for benzene and Tris in connection with its proceedings for regulating these substances. 42 Fed. Reg. 18850, 18851 (April 8, 1977)(Tris); 43 Fed. Reg. 21838, 21845 (May 19, 1978)(Benzene).

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[22] *See, e.g.*, Testimony of Donald Kennedy (Administrator, FDA), OSHA Cancer Policy Record, Tr. 513-14. For example, in connection with its proposed tolerance level for aflatoxin in consumer peanut products under Section 406 of the Food, Drug, and Cosmetic Act (21 U.S.C. § 346), FDA conducted a risk assessment to provide part of the basis for developing a final rule. 43 Fed. Reg. 8808 (March 3, 1978).

[23] Testimony of Donald Kennedy, OSHA Cancer Policy Record, Exh. 183-10 at 11 (Because "not all carcinogens are equally potent and . . . there are vast differences in the levels of human exposure, . . . I urge OSHA to use quantification of risk as one component of decision-making.").

[24] The so-called "DES proviso" to the anticancer clauses in Sections 409(c)(3)(A), 512b(d)(1)(H) and 706(b)(5)(B) of the Food, Drug and Cosmetic Act requires that there be no residue of a carcinogen in the edible portions of food-producing animals. 21 U.S.C. §§ 348(c)(3)(A), 360b(d)(1)(H), & 376(b)(5)(B). Because increasingly sensitive analytical techniques threaten to turn these requirements into a ban on the use of valuable growth-stimulants in animal feed, FDA proposes to utilize quantitative risk estimation to determine the residue concentration that is expected to present a cancer risk of one-in-one million over a lifetime, and to require measurement techniques which will not detect lower concentrations. 44 Fed. Reg. 17070 (March 20, 1979).

The experience of EPA, FDA, CPSC and other federal agencies[25] in using quantitative risk assessments to develop regulations for carcinogens reflects the widespread and long-standing use of similar techniques in many areas of regulation.[26] In short, there is simply no foundation for any claim that these procedures will contribute nothing or will result in regulatory paralysis.

C. The Experience of OSHA

Any claim by OSHA that quantitative risk estimation is impossible or not useful is fully laid to rest when OSHA's own practices are examined. Although hardly a model of consistency, OSHA, both in public declarations and in developing other standards, has recognized the value of risk assessment, and even cost-benefit analyses.

Perhaps the best example of OSHA's ability to assess quantitatively the benefits of its standards is a recent report to Congress in which OSHA attempts

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[25] As far back as 1960, for example, the Nuclear Regulatory Commission (then the Atomic Energy Commission) issued regulations concerning occupational and ambient exposure to cancer-causing radiation which were based on quantitative risk estimates. *See* 25 Fed. Reg. 8595 (September 7, 1960); FEDERAL RADIATION COUNCIL, BACKGROUND MATERIAL FOR THE DEVELOPMENT OF RADIATION PROTECTION STANDARDS, Report No. 1 (May 13, 1960). *See also*, 35 Fed. Reg. 18385 (December 3, 1970); NATIONAL BUREAU OF STANDARDS, MAXIMUM PERMISSIBLE AMOUNTS OF RADIOISOTOPES IN THE HUMAN BODY AND MAXIMUM PERMISSIBLE IN THE AIR AND WATER, NBS Handbook 69 (April 1959).

[26] The National Highway Traffic Safety Administration ("NHTSA") and the Federal Aviation Administration ("FAA"), for example, have for years conducted careful studies of the risks and benefits of alternative regulations in the area of transportation safety. For example, NHTSA employed detailed risk and benefit data in connection with its motor vehicle safety standard for air bags. *See* 42 Fed. Reg. 34288, 34298-99 (July 5, 1977); 41 Fed. Reg. 31860 (July 30, 1976). The FAA uses a similar approach. *See, e.g.*, FAA, *Establishment Criteria for Airport Traffic Control Towers*, Report No. ASP-75-4, (U.S. Dep't of Transp., October 1975). *See also* n.2 at 1c, *supra*.

to justify its 1978 standard for cotton dust.[27] In this Report, OSHA estimated the risk of exposure at various levels and in various work operations and projected the costs and benefits (expressed as the number of cases of disease avoided annually) of the alternative exposure limits that it examined.[28] OSHA's presentation to Congress included elaborate and detailed analyses of the incremental costs and benefits of possible alternative standards,[29] as well as "marginal analyses . . . of the major industry subgroups" under each alternative.[30] OSHA rejected more stringent standards on the ground that they would have been less "cost-effective" than the one it had chosen and they would have required "disproportionately large compliance costs for relatively small health gains."[31]

The Cotton Dust Report is a concrete reflection of the increasing recognition by OSHA's leading spokespersons that risk quantification is a valuable tool in arriving at regulatory decisions. Thus, in a recent speech, Secretary of Labor Marshall firmly declared that "we are beginning to quantify the benefits of regulations that improve . . . worker safety and health," and added:

> It does no harm to our cause to acknowledge both the costs and benefits of regulation. It helps us decide more intelligently

[27] U.S. Dep't of Labor, *Report to the Congress—Cotton Dust: Review of Alternative Technical Standards and Control Technologies* (May 14, 1979).

[28] *Id.* 81-97.

[29] *See, e.g., id.* Table VI-1 at p. 82.

[30] *Id.* 81.

[31] *Id.* 65. The textile industry has challenged the cotton dust standard on the ground, *inter alia*, that it would be much more costly and would provide fewer health benefits than OSHA has claimed, thereby being far less cost-effective as well.

> which goals are more important and how to reach them.[32]

Dr. Eula Bingham, the head of OSHA, took a similar position in recent testimony before the Senate Appropriations Committee.[33]

These recent actions and pronouncements reflect earlier efforts by OSHA to use quantitative and qualitative information on health risks in developing occupational health standards.[34] For example, in its 1974 rule setting standards for 14 different carcinogens, OSHA significantly modified the regulatory requirements based on careful distinctions concerning the carcinogenic potencies of the substances under consideration.[35]

[32] March 24, 1979, speech of Secretary of Labor Ray Marshall to the League of Women Voters at 3, 8. *See* OCCUP. SAFETY & HEALTH REP. (BNA) 1606 (March 29, 1979).

[33] Dr. Bingham testified that OSHA does "incremental cost-benefit analyses . . . all the time," and that such analyses are a "key factor" in developing a new regulation. *Hearings on Dep'ts of Labor and Health, Education and Welfare and Related Agencies' Appropriations for Fiscal 1980, before the Senate Comm. on Appropriations*, 96th Cong., 1st Sess. 490 (Feb. 8, 1979).

[34] As far back as 1974, OSHA recognized that the benefits of its standards "cannot be estimated with certainty," but nevertheless stated that it was "exploring methods to obtain the data necessary to begin *quantitatively* evaluating" "the entire range of financial, social, and other real but indirect benefits which accrue" from its standards. *The President's Report on Occupational Safety and Health* 15 (OSHA Annual Report 1974) (emphasis added).

[35] In that case, OSHA excluded from the coverage of its standards some exposure to eight of the fourteen carcinogens involved because "the record contain[ed] very little information" concerning the "carcinogenic potentiality" of exposure at the levels involved and concerning the economic benefits of the substances. 39 Fed. Reg. 3756, 3759 (Jan. 29, 1974). By contrast, more stringent controls were imposed on the remaining six

(footnote continued on next page)

More recently, OSHA purported to use a risk estimation/cost-effectiveness approach in developing its Lead Standard. In that case, as in the case of its Cotton Dust Report, OSHA purported to provide an elaborate incremental analysis of the relative health benefits (in terms of reduced blood-lead levels) that would be realized at various exposure levels.[36] The estimated benefits of various alternatives were compared not only to the current level but to each other.[37]

In sum, the present contention of OSHA's lawyers that risk assessment is not a useful regulatory technique simply cannot be credited. The substantial experience of other federal health agencies, and even that of OSHA itself in several instances, establishes that these procedures are both feasible and immensely useful in helping to clarify and rationalize regulatory decisionmaking for carcinogens and other health hazards.

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substances because they were "known to be potent carcinogens." *Id.*

Similarly, OSHA used quantitative risk information in connection with its 1974 proposed noise standard. Bolt, Baranack & Newman, Inc., *Economic Impact Analysis of Proposed Noise Control Regulation*, Rep. No. 3246, April 21, 1976, prepared for the U.S. Dep't of Labor, OSHA. *See* 29 Fed. Reg. 37773 (Oct. 24, 1974).

[36] *See* 43 Fed. Reg. 52952, 52967-72 (November 14, 1978); 43 Fed. Reg. 54354, 54427-40 (November 21, 1978).

[37] Interestingly enough, OSHA concluded that this "evaluation of the relationship between the costs and benefits [of the Lead Standard] meets the test enunciated by the Fifth Circuit" in the case now before this Court. 43 Fed. Reg at 54431.

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OCTOBER TERM, 1978

Nos. 78-911 & 78-1036

INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
Petitioner,
v.
AMERICAN PETROLEUM INSTITUTE, *et al.*,
Respondents.

RAY MARSHALL, SECRETARY OF LABOR,
Petitioner,
v.
AMERICAN PETROLEUM INSTITUTE, *et al.*,
Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Fifth Circuit

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BRIEF FOR RESPONDENTS THE RUBBER MANUFACTURERS ASSOCIATION, INC., *et al.*

(Relating To The Dermal Contact Issue)

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In the Supreme Court of the United States

OCTOBER TERM, 1978

Nos. 78-911 & 78-1036

INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*,
Respondents.

RAY MARSHALL, SECRETARY OF LABOR,
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*,
Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Fifth Circuit

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BRIEF FOR RESPONDENTS THE RUBBER MANUFACTURERS ASSOCIATION, INC., *et al.*

(Relating To The Dermal Contact Issue)

QUESTION PRESENTED

The Occupational Safety and Health Administration ("OSHA"), petitioner in No. 78-1036, has presented two questions stemming from the decision of the court of appeals setting aside the airborne exposure provisions and the dermal contact sections of OSHA's benzene standard.[1] This brief addresses only the second of those questions, relating to the dermal contact sections of the benzene standard.[2] OSHA has posed the second question as a hypothetical inquiry divorced from the facts of this case. Restated to reflect the decision of the court below, that question is:

> Whether OSHA, in promulgating as part of the benzene standard a ban on dermal contact with liquids containing even small or trace amounts of benzene, was entitled to rely solely on outdated and inconclusive data while failing to obtain readily available evidence from "research, demonstrations, [and] experiments", as required by Section 6(b)(5) of the Occupational Safety and Health Act of 1970.

STATEMENT OF THE CASE[3]

A. Introduction

This case presents questions concerning two separate and essentially unrelated provisions of OSHA's Permanent Standard for Occupational Exposure to Benzene (the "benzene standard"). The first of these provisions regulates airborne exposure to benzene and requires employers to assure that no employee is exposed to an airborne concentration of benzene in excess of 1 part benzene per million parts of air (1 ppm) as an 8-hour time-weighted average. The second of the provisions operates independently of the airborne exposure limit and bans dermal contact with benzene or substances containing even small amounts of benzene.[4] (29 C.F.R. § 1910.1028(c)(2), Pet. App. 36a.)

Respondents the Rubber Manufacturers Association and six individual rubber companies (collectively "rubber companies")[5] are affected primarily by the second of the two major provisions of the benzene standard—the ban on dermal contact. Rubber companies manufacture tires, tennis balls, and a range of other products[6] from natural and synthetic rubber. In doing so, they use petroleum

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[1] The question presented by the Industrial Union Department, AFL-CIO ("IUD"), petitioner in No. 78-911, is essentially the same as the first question presented in No. 78-1036.

[2] The Brief for Respondents American Petroleum Institute, *et al.* (the "API Brief"), deals with the decision of the court below setting aside OSHA's permissible airborne exposure limit for benzene. Respondents The Rubber Manufacturers Association, *et al.* support the statement of issues and legal conclusions set out in that Brief. In turn, the respondents filing that Brief support the statements and arguments presented here. *See* API Brief, at 2 n. 2.

[3] Several abbreviations are used in this brief. "Pet. App." refers to the separately bound Appendix to the petition in No. 78-911. "A." refers to the Joint Appendix filed in these cases. The complete record of OSHA's proceedings on the original benzene standard and the June 1978 amendment to the standard is on file with this Court. References to the record of the original standard are as follows: Transcript—"Tr."; Exhibit—"Ex." References to the record of the amendment to the benzene standard are: Transcript—"Amend. Tr."; Exhibit—"Amend. Ex."

[4] A related provision of the standard requires employees to wear protective clothing and equipment where dermal or eye contact may occur. 29 C.F.R. § 1910.1028(h), Pet. App. 42a. The sections of the standard banning dermal contact (29 C.F.R. § 1910.1028(c)(2)) and requiring the use of protective clothing and equipment (29 C.F.R. § 1910.1028(h)) are referred to collectively as the "dermal contact sections" or the "dermal contact provisions".

[5] The six companies are The Armstrong Rubber Company, The Firestone Tire & Rubber Company, The General Tire & Rubber Company, The B. F. Goodrich Company, The Goodyear Tire & Rubber Company, and Uniroyal, Inc.

[6] These other products include such diverse items as inner tubes, hoses, v-belts, conveyor belts, adhesives, cements, tennis shoes, shoe products, and health and hospital products. *E.g.*, Amend. Ex. 46-59, at 1.

solvents, cements and other materials which contain benzene in small or trace amounts (less than 1.0 percent) as an unintentional ingredient. These solvents, cements and other materials are used as tackifying agents to enhance adhesion of various components of rubber company products (such as tire plies or tennis ball covers) during the manufacturing process. During the manufacture of such rubber products, there is necessary periodic skin contact with these tackifying agents.

The fact that skin contact with solvents containing small amounts of benzene cannot be avoided in rubber company manufacturing operations is not in dispute. Indeed, OSHA conceded to the court below that the rubber companies had "advanced a real problem" in contesting the feasibility of compliance with the dermal contact sections.[7] And in announcing the amendment to the benzene standard, OSHA admitted that:

> *[I]n tire-building, the record evidence shows that at present there are no suitable methods available to prevent skin contact with solvents containing a small amount of benzene.* (A. 266 (emphasis added).)

Especially in view of the record and OSHA's own prior statements, rubber companies were surprised by, and strongly disagree with, OSHA's characterization of the second issue in this case as involving simply a "protective clothing requirement". (OSHA's Brief at 4, 13, 39, 74; *compare id.* at 15, 25, 35, 82 ("dermal prohibition").) The dermal contact provisions operate to ban skin contact with liquids containing even small amounts of benzene.[8] Where it is not possible to use protective clothing and equipment—as is the case with rubber manufacturing operations—the dermal provisions among other things would effectively bring "domestic tire production to a virtual standstill."[9] It is for that reason that rubber companies sought review of OSHA's decision to ban dermal contact with liquids containing small amounts of benzene, without a proper scientific or factual basis for doing so.

[7] A. 231, Amend. Ex. 32-A-3 (OSHA's Supplemental Memorandum in Opposition to Stay, Apr. 11, 1978) at 67. There is no factual basis whatsoever for the assertion in OSHA's Brief that "[i]t is unquestioned that the use of protective clothing to prevent dermal or eye contact with benzene-bearing liquids is feasible". OSHA's Brief at 81 n. 64. Given the uniform record evidence to the contrary, including OSHA's own prior statements, this assertion in OSHA's Brief is inexplicable.

Indeed, the infeasibility for rubber companies of compliance with the dermal contact sections was a principal issue raised before the court of appeals. As discussed *infra*, at 16, the court of appeals did not reach that issue.

B. The Original Benzene Standard

OSHA's Brief describes in part the record of the original benzene proceeding respecting the dermal contact sections. (OSHA's Brief at 25-28.) While rubber companies do not believe that OSHA's statement fully sets forth the record evidence in that regard, that evidence is summarized in rubber companies' Joint Memorandum in Opposition to the petitions for certiorari (at 8-12). In the interest of brevity, this truncated counterstatement of the case begins with the issuance of the benzene standard by OSHA on February 3, 1978.

In contrast both to OSHA's emergency temporary standard ("ETS") for benzene and to its proposed benzene standard, each of which contained exclusions for

[8] As described *infra*, at 9-13, OSHA has varied the extent of the ban on dermal contact since the issuance of the benzene standard. The standard as originally adopted by OSHA prohibited all dermal contact with any liquid containing any amount of benzene. In the first five months following adoption of the standard, OSHA twice modified the extent of the ban on dermal contact. However, the court of appeals stayed the entire benzene standard before its effective date, and the standard has never gone into effect.

[9] A. 207, Amend. Ex. 32-F-2 at 22.

mixtures containing small amounts of benzene,[10] OSHA's permanent standard provided no such exclusion. The permanent standard banned all dermal contact with liquid mixtures containing any amount of benzene (29 C.F.R. § 1910.1028(c)(2), Pet. App. 36a), and required employees to wear protective clothing and equipment where dermal exposure might occur (29 C.F.R. § 1910.1028(h), Pet. App. 42a). It also required employers to affix "Cancer Hazard" labels on *all* containers of *all* products containing *any* amount of benzene. (29 C.F.R. § 1910.1028(k), Pet. App. 47a-48a.)[11]

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[10] The ETS exempted from its coverage mixtures containing 1.0 percent benzene or less. 42 *Fed. Reg.* 22515, 22525 (May 3, 1977), Ex. 1. Respecting dermal contact, the effect of that exemption was to permit employees to have dermal contact with mixtures containing 1.0 percent benzene or less. Because rubber company manufacturing operations use liquids containing less than 1.0 percent benzene, those operations were not affected by the dermal contact sections of the ETS. The proposed standard, like the ETS, contained a volume percentage exclusion, exempting from the standard's coverage work operations where "the only exposure to benzene is from liquid mixtures containing 1% (0.1% after one year from the effective date of this standard) or less of benzene by volume, or the vapors released from these liquids." 42 *Fed. Reg.* 27451, 27460 (May 27, 1977), Ex. 4.

[11] Because benzene is present in minute quantities in water supplies throughout the country, as well as in everyday foods and elsewhere throughout our society, as initially promulgated OSHA's standard would have produced absurd results. It would have imposed a ban on drinking water in workplaces in the United States and would have required that all workplace drinking fountains bear a "readily visible and legible" label stating: "CAUTION—CONTAINS BENZENE—CANCER HAZARD". 29 C.F.R. § 1910.1028(b), (c)(2), and (k)(2)-(4), Pet. App. 36a, 42a, 47a-48a. *See* the opinion of the court of appeals, Pet. App. 12a, 581 F.2d at 500. For the same reason, employees would have been barred from washing their hands or taking showers at workplaces. Solid materials would also have been affected. For example, the same label would have been required to be affixed to all cans of tennis balls made in the United States, but not to cans of tennis balls manufactured abroad.

In announcing the permanent standard, OSHA offered no explanation for its last-minute and unexpected elimination of the exclusion for liquid mixtures with small amounts of benzene. OSHA did not even mention that removal of the exclusion had the effect of drastically changing the scope and impact of the dermal contact provisions in particular. The Agency imposed the draconian prohibition against dermal contact even though in the preamble announcing the permanent standard, it acknowledged that "[i]nhalation is the primary route of entry of benzene in man." (Pet. App. 78a.) OSHA made its decision on the basis of its "policy" (Pet. App. 192a), while conceding that it did not know whether benzene is absorbed through intact skin:

> The record evidence on the effect of liquid benzene on the eyes or the skin is *extremely limited.* No scientific data as to the effects of benzene on the eyes was presented during the rulemaking proceeding. The few studies of skin effects on animals and humans are *not definitive* as to the extent of benzene that is absorbed through the intact skin or as to the comparative rate of absorption through damaged skin. (Pet. App. 193a (citations omitted) (emphasis added).)

Consistent with this lack of knowledge, the medical surveillance guidelines for benzene contained in an appendix to the standard stated that "[b]enzene is primarily an inhalation hazard" and that "*[t]he extent of absorption through the skin is unknown.*" (Pet. App. 58a (emphasis added).)

Rubber companies filed a request with OSHA for a stay of the dermal contact provisions and certain other sections of the standard. That request focused particularly on the fact that it was not feasible for rubber companies to continue their manufacturing operations in compliance with the ban on dermal contact. Manufacturing operations for tires, tennis balls, v-belts, conveyer belts, hose and other products necessarily involve dermal

contact with solvents containing small amounts of benzene (less than 1.0 percent.)[12]

The manufacture of tires, for example, involves the use of petroleum-based solvents as tackifying agents essential to the tire building process. (A. 190-191, 206-207, 210-212, 217-219, 225; Amend. Tr. 87-89, 160-167, 185-186.) Layers of materials ("plies") swabbed with solvent are manually built up to construct tires. (*Id.*) To achieve the precision of attachment and adhesion critical for tire uniformity and compliance with government tire safety standards, full use and dexterity of the workers' hands is required. (*Id.*) Skin-tight gloves impervious to most liquids cannot be used; they would dissolve or become tacky upon contact with petroleum solvents and actually lead to greater hazards and exposure. (A. 191, 207, 212, 219, 225, 228.)

In tire building and other rubber company operations, there are no suitable substitutes for petroleum solvents which contain small amounts of benzene as a contaminant. (A. 199, 218; Amend. Tr. 115-116.) Despite repeated requests by rubber companies, it is not possible to obtain from suppliers solvents which do not contain trace amounts of benzene. (A. 207, 212, 218, 225, 228; Amend. Tr. 87, 153, 168, 186-187, 208-209, 213.) While the benzene content of such solvents has declined in recent years, it remains typically above 0.1 percent and in some instances exceeds 0.7-0.8 percent. (A. 199, 225, 228; Amend. Tr. 131, 151-153, 175-178, 196-197.) Very substantial quantities of solvents, exceeding 110 million gallons annually, are purchased by rubber companies throughout the United States from a number of suppliers. Moreover, the benzene content of solvents varies among

[12] *E.g.*, Request for Stay on Behalf of Rubber Companies (Mar. 3, 1978), Amend. Exs. 27-E.1 and E.2; Amend. Ex. 46-59, at 3-9; A. 206, 211, 212, 217, 222-223, 228; Amend. Tr. 78-82, 87-89, 132-133, 160-167, 212.

suppliers, among different plants of the same supplier, and even among different shipments from the same plant of the same supplier. (Amend. Tr. 117-118, 175-178, 200-201, 207-209.)

In response to the various requests for stay, on March 8, 1978 OSHA informed rubber companies and other industry respondents that it was "going to stay the standard as it applie[d] to work operations where the sole exposure to benzene is from mixtures containing 0.1 percent or less benzene." (A. 204.)

C. The Amendment To The Standard

Thereafter on March 28, 1978, OSHA published a notice of its limited stay of the standard[13] and of a rulemaking proceeding to amend the standard. (43 Fed. Reg. 12890-12891, Amend. Ex. 4.)[14] That notice proposed an amendment to exclude from the standard l quid mixtures containing 0.1 percent or less of benzene. The announcement sought to limit the points at issue in the new administrative proceedings to nine specific questions, and interested persons were instructed to address the proposed percentage exclusion only as it related to "airborne concentrations" of benzene. (*Id.* at 12891.) Notwithstanding OSHA's lack of evidence as to whether dermal contact with liquid mixtures containing small amounts of benzene constituted a health hazard, OSHA sought no evidence on that issue. Moreover, in the administrative proceedings OSHA refused to consider such evidence even

[13] OSHA's stay had no legal effect. The entire benzene standard had previously been stayed by the court of appeals.

[14] OSHA further modified the scope of the standard by means of a "correction" document published March 31, 1978. 43 *Fed. Reg.* 13561-13563, Amend. Ex. 3B. Among other changes, OSHA "corrected" the preamble to the standard so as to exclude from the standard solids containing benzene (other than pure solid benzene, which generally exists only in scientific laboratories). One effect of this "correction" was to exclude cans of tennis balls and boxes of tennis shoes from the requirement that they be labeled as a "CANCER HAZARD". *See supra*, at 6 n. 11.

after the rubber companies expressly warranted to the Agency that Dr. Howard Maibach[15] was conducting a study of issues relating to dermal exposure to benzene.

During the new rulemaking proceeding, the rubber companies informed OSHA explicitly that Dr. Maibach had been commissioned to conduct a skin absorption test. (Amend. Tr. 71.) Dr. Maibach's own description of his testing program was received into evidence at the hearing on the proposed amendment to the standard. (Amend. Tr. 71-73.)[16] Nevertheless, Grover Wrenn, OSHA's Director of Health Standards Programs, flatly stated at the hearing that OSHA would not await the results of such a study even though these results could be made available to it within 180 days. (A. 185.)[17] Mr. Wrenn further testified that OSHA did not have any independent plans to obtain data to determine whether a hazard existed from dermal exposure to mixtures containing small amounts of benzene. (A. 183-184.)

Rubber companies participated extensively in the new rulemaking and presented detailed evidence on the infeasibility of complying with the dermal contact sections as proposed in the amendment. (*E.g.*, A. 187-201, 205-229, 232-238; Amend. Ex. 46-41, 46-58, 46-59, 46-80, 74, 75, 78.) Among other things, rubber companies strongly urged OSHA to provide in the standard for at least a parity of requirements for airborne and dermal exposure.

[15] Professor of Dermatology, University of California Medical Center.

[16] Dr. Maibach was unable to appear in person because of his teaching schedule.

[17] The question to Mr. Wrenn was based on a 180-day period because such a period had been specified in a pending proposal by OSHA for a standard relating generically to substances posing a potential carcinogenic risk. *See infra* at 42 n. 78.

Dr. Maibach has now in fact completed his study of the absorption of benzene in which he performed straightforward and reliable tests using radioactive-tagged benzene with rhesus monkeys. *See infra*, at 35-36 n. 69.

The companies advocated adoption of a special "dermal action level" that would permit dermal contact with liquids containing small amounts of benzene, similar in concept to the "action level" already in the standard for airborne exposure to benzene.[18] (Amend. Ex. 46-59, at 1-3; A. 190, 192, 213, 235-237; Amend. Tr. 67-68, 76, 95, 98-99, 136-137, 159, 170, 188-191, 212-215.) Such a dermal action level would provide an exemption only for dermal contact with liquids containing small amounts of benzene.[19]

In support of the proposed dermal action level, The B. F. Goodrich Company presented the results of experimental work and calculations performed to determine the relationship between entry of benzene into man through inhalation of airborne benzene and possible skin absorption of benzene contained in rubber solvent. Based on the existing literature, Goodrich concluded that the maximum absolute benzene absorption from a tire builder's use of rubber solvent containing 1.0 percent benzene (which is higher than the 0.5 percent or less benzene normally contained in such solvents) was only one-third of the permitted airborne benzene exposure at the 1 ppm permissible exposure limit of the benzene standard. (A. 193-197, 234-238.)[20] Even though an OSHA representative

[18] An employer is exempt from many of the requirements of the standard if airborne concentrations do not exceed the "action level" of 0.5 ppm. *See* 29 C.F.R. § 1910.1028(b), (e)(3), Pet. App. 35a, 37a-38a.

[19] Where solvents were used with a benzene content greater than the across-the-board percentage-exclusion level then proposed by OSHA, but less than the dermal action level, the user of the solvent would have been required to comply with the airborne exposure provision.

[20] The Goodrich calculations were based on skin absorption data contained in the only study in the record showing *any* absorption of benzene through the skin (using 100% benzene, rather than solvent containing benzene). A. 107-120. The authors of that study described their results as reflecting the "extreme case" (A. 117) and OSHA itself has described the study as not "definitive". OSHA's Brief at 27 n. 29.

[Footnote continued on page 12]

stated at the hearing that Goodrich's experiment was "fascinating" and that "if it were true, it could have some effect on [the suggested] dermal action level" (A. 194), the suggested dermal action level was ignored by OSHA (*e.g.*, Amend. Tr. 62-63) and OSHA did not even advert to the Goodrich information in announcing the amendments to the benzene standard. OSHA adopted a percentage exclusion amendment without revising in any other way the harsh dermal contact provisions of the standard.

OSHA announced the amendments to its benzene standard in late afternoon on the day before oral argument in the court of appeals.[21] (Pet. App. 2a n.4, 581 F.2d at 496 n.4.) For three years OSHA exempted liquid mixtures containing 0.5 percent or less benzene from the provisions of the standard, and thereafter mixtures containing 0.1 percent or less benzene.[22] In doing so, OSHA

[20] [Continued]

Skin absorption data from Dr. Maibach's studies show that the study used by Goodrich led Goodrich to substantially *overestimate* skin absorption of benzene. Dr. Howard Johnson recently completed a comparative study of the human systemic exposure to benzene resulting from dermal and inhalation exposure, using Dr. Maibach's skin absorption data. Dr. Johnson's study was furnished to OSHA on July 24, 1979 and a copy has been lodged with the Clerk of this Court. Dr. Johnson compared conditions of dermal exposure in passenger tire manufacturing operations using solvent containing 0.35 percent benzene with conditions of inhalation exposure to air with 1 ppm benzene. He concluded that maximum pulmonary absorption of benzene would be 15 times greater than maximum dermal absorption. Dr. Johnson's report further found that at OSHA's currently-effective 10 ppm limit of benzene in air, maximum pulmonary absorption of benzene would be 150 times greater than maximum dermal absorption.

[21] The court of appeals and the private litigants learned of the amendments that afternoon during a pre-argument conference held in the chambers of one of the circuit judges assigned to the panel of the Fifth Circuit hearing the case.

[22] OSHA also exempted certain previously-packaged mixtures from the standard's labeling provisions.

recognized that "in tire-building . . . there are no suitable methods available to prevent skin contact with solvents containing a small amount of benzene." (A. 266.) OSHA nonetheless chose not to modify the dermal contact provisions, but rather to rely on the across-the-board percentage exclusion to provide a modicum of temporary relief for three years.[23] For the longer term, OSHA speculated as to the possibility of increased production of solvents containing less than 0.1 percent benzene and other unspecified technological developments (A. 266), without citing any factual basis for its speculation and in the face of substantial evidence to the contrary. OSHA cited no new health evidence in support of the amendment.

D. The Decision Of The Court Of Appeals

On October 5, 1978, the court of appeals issued its decision granting the petitions for review of the benzene standard, setting aside the airborne permissible exposure limit and the dermal contact provisions, and also vacating the remaining provisions of the standard.

Specifically, the court of appeals vacated the dermal contact provisions on two separate and alternative grounds.[24] The court noted at the outset that OSHA's prohibition against dermal contact was based on " 'OSHA's *policy* that, in dealing with a carcinogen, all potential routes of exposure (*i.e.*, inhalation, ingestion, and skin absorption) be limited to the extent feasible.' "

[23] Rubber companies can in most cases obtain solvents at or less than the 0.5 percent level for use in their Eastern, Southern and Midwestern tire and other manufacturing plants. Even for these plants, the companies often are close to or at the 0.5 percent level without any margin for deviation. A. 189-190; Amend. Tr. 117, 166-168. For West Coast plants, however, the 0.5 percent level could not be met, since in some instances suppliers could only meet a limit of 0.7 percent benzene in suitable solvents. Amend. Tr. 168, 176. These differences in solvents stem from available crude oil supplies. *Id.* at 168.

[24] The court did not reach the issue of feasibility of the dermal contact provisions, the third asserted ground for setting the provisions aside. *See infra*, at 16.

(Pet. App. 22a (quoting 43 Fed. Reg. 5948, Pet. App. 192a), 581 F.2d at 505 (emphasis added).) Rejecting OSHA's claim that its decision to prohibit dermal contact with liquid mixtures containing small amounts of benzene was supported by "substantial evidence",[25] the court stated that:

> OSHA's decision to regulate on the basis of dated, inconclusive data when modern experimental methods can quickly and efficiently provide reliable information contravenes the directive from Congress to promulgate standards on the basis of the "best available evidence," "research, demonstrations, experiments, and such other information as may be appropriate," and "the latest available scientific data in the field." 29 U.S.C.A. § 655(b)(5). This is not a case where there is testimony that additional research could be attempted, but might not shed new light on a subject. (Pet. App. 26a-27a, 581 F.2d at 507.)

[25] OSHA incorrectly asserts that the court of appeals found OSHA's adoption of the dermal contact sections to be supported by "substantial evidence". OSHA's Brief at 74. To the contrary, the court, after reviewing the "dated, inconclusive data" relied upon by OSHA, stated that "OSHA's finding that dermal contact with benzene poses a cancer risk *could* pass muster" if that had been the only evidence in the record. Pet. App. 25a, 581 F.2d at 507 (emphasis added). The court then considered Dr. Maibach's testimony describing available and reliable experimental techniques which could resolve within a relatively short term the issue of whether human skin absorbs benzene, and found that Dr. Maibach's "additional evidence remove[d] the support for OSHA's actions." *Id.*

Indeed, at a prior point in its opinion, where the court summed up its ruling on the dermal contact provisions, the court stated:

> The record therefore fails to support the finding that benzene is absorbed through the skin. Since entry to the body by dermal contact was not established, the record will not support a finding that the prohibition of all dermal contact with benzene . . . [is reasonably necessary]. Pet. App. 23a-24a, 581 F.2d at 506.

Moreover, a finding like that which the government suggests was made would have required the court of appeals to reach the feasibility issue, which the court specifically reserved.

In reaching that conclusion, the court reviewed in detail the record evidence on the issue of skin absorption of benzene. That review encompassed not only the "dated, inclusive" data, but also Dr. Maibach's "unrefuted testimony" as to "simple experimental techniques" that were reliable and accurate and that could provide "readily available" factual information relating to benzene absorption. On the basis of that detailed factual review, the court held that:

> OSHA's choice to rely on old and inconclusive evidence that there is a possibility of absorption of benzene through the skin which might cause cancer is in clear disregard of the congressional directive as to the kinds of evidence OSHA is required to consider. Therefore, the provision of the standard prohibiting dermal contact with liquid benzene cannot stand on the present record. (Pet. App. 27a, 581 F.2d at 508.)

The court of appeals also vacated the dermal contact provision on the ground that it was not "reasonably necessary" as required by Section 3(8) of the Occupational Safety and Health Act of 1970 (the "Act"), 29 U.S.C. § 652(8). OSHA had sought in the court of appeals to justify the dermal contact prohibition as an adjunct to the permissible airborne exposure limit and on the basis of a concern for dermatitis. Both contentions were rejected. The court's analysis of the record led it to conclude that the argument of dermatitis "appear[ed] to be a post hoc rationalization for the dermal contact prohibition since it was not a significant part of OSHA's reasoning process that led to [that] provision." (Pet. App. 22a, 581 F.2d at 505.) Because review of the standard "must be of the reasoning process of the agency at the time it promulgated the standard based on the record before it" (Pet. App. 23a, 581 F.2d at 506),[26] the court refused to

[26] As authority for this principle, the court cited *Dry Color Mfrs.' Ass'n* v. *Department of Labor*, 486 F.2d 98, 104 n.8 (3d Cir. 1973), which in turn cites and relies on this Court's decisions in

give weight to the newly proffered argument on dermatitis. And noting that the record did not support OSHA's finding that benzene is absorbed through the skin, the court determined that:

> [T]he record will not support a finding that the prohibition of all dermal contact with benzene will result in quantifiable benefits in terms of a reduced risk of leukemia justifying the costs of the provision. Thus reasonable necessity is lacking here too. (Pet. App. 23a-24a, 581 F.2d at 506.)

Rubber companies had raised the infeasibility of the dermal contact provisions as a third ground for setting the provisions aside. However, the court of appeals did not reach the issue of whether OSHA's ban on dermal contact was "feasible" within the meaning of Section 6(b)(5) of the Act, 29 U.S.C. § 655(b)(5), stating that the amendment to the standard on June 21, 1978, "significantly affect[ed] the feasibility issue . . . ." (Pet. App. 23a, 581 F.2d at 506.)[27] As the court set aside the dermal contact provisions on the two other grounds, it could decide the case without ruling on the feasibility issue.[28]

Citizens to Preserve Overton Park v. *Volpe*, 401 U.S. 402, 419 (1971), *National Labor Relations Board* v. *Metropolitan Life Ins. Co.*, 380 U.S. 438, 443-444 (1965), and *Burlington Truck Lines* v. *United States*, 371 U.S. 156, 168-169 (1962), along with *United States* v. *Allegheny-Ludlum Steel*, 406 U.S. 742, 756-757 (1972).

[27] Because the amendment to the standard had been issued literally on the eve of oral argument, at the close of the argument the court of appeals had ordered the parties to file supplemental briefs on an expedited basis directed to the effect of OSHA's amendment on the litigation.

[28] *See* OSHA's Brief at 31 n. 32. OSHA is simply wrong when, at a subsequent point in its brief, it asserts that the feasibility of the dermal contact provisions was and is "unquestioned". *Id.*, at 81 n. 64. *See supra*, at 4 n. 7.

SUMMARY OF ARGUMENT

The court of appeals correctly decided that OSHA's decision to ban dermal contact with liquids containing even small or trace amounts of benzene was not supported by "substantial evidence", as required by Section 6(f) of the Act, 29 U.S.C. § 655(f), and was not "reasonably necessary" to protect workers' health, within the meaning of Section 3(8) of the Act, 29 U.S.C. § 652(8).

Whether there is substantial evidence supporting OSHA's ban on dermal contact must be determined with reference to the standard-setting criteria in Section 6(b)(5) of the Act, 29 U.S.C. § 655(b)(5). Those criteria reflect a clear Congressional mandate that OSHA standards be properly premised on a factual, scientific basis. Section 6(b)(5) directs that OSHA standards for toxic materials or harmful physical agents "*shall be based upon research, demonstrations, experiments, and such other information as may be appropriate*" (emphasis added), and requires that OSHA shall consider "the latest available scientific data in the field . . . ." These specific evidentiary criteria were added to Section 6(b)(5) in the Senate, after an earlier, more general House Committee version of that section was criticized as allowing standards to be based on " 'views and arguments' rather than probative evidence." (*See infra*, at 28.)

The legislative history of the Act is directly contrary to OSHA's assertion that it has unfettered discretion to determine whether it is appropriate to obtain factual information to support particular provisions of its standards. By requiring that OSHA act from "research, demonstrations, [and] experiments", Congress expressed its intent that OSHA standards be scientifically-based and factually supported. The emphasis on the need for scientific research in standard-setting meshes with the "research" provisions of the Act, which give OSHA the

means to obtain necessary factual information by contracting directly for scientific research or other studies (Section 20(c)) and which created a new National Institute of Occupational Safety and Health to conduct "research, experiments, and demonstrations relating to occupational safety and health" (Section 20(a)(1); *see* Sections 20(e), 22).

In the face of the specific mandate of Section 6(b)(5), OSHA has shown an evident lack of concern for addressing the question of skin absorption of benzene. OSHA's own statement of its reasons for the ban on dermal contact is startling for its lack of any significant scientific or factual basis. OSHA seeks to justify the dermal contact prohibition based on the Agency's "policy", while admitting that the record evidence is "extremely limited" and the "few studies" are "not definitive" (Pet. App. 192a-193a), and at the same time acknowledging that the "extent of [benzene] absorption through the skin is unknown" (Pet. App. 58a). Yet on that fact-bereft basis OSHA banned skin contact with liquids containing only trace amounts of benzene, thereby placing greater limitations on skin contact than on airborne exposure, even though OSHA recognized the only evidence of a carcinogenic hazard from benzene related to inhalation.

Throughout the entire course of the proceedings on the benzene standard, OSHA has ignored, and continues to ignore, the "unrefuted testimony" (Pet. App. 27a, 581 F.2d at 507, 508) of Dr. Howard Maibach as to readily available skin absorption data. Dr. Maibach testified that simple, straightforward and reliable experimental techniques using radioactive-tagged benzene can determine within a short time (six to twelve weeks) whether benzene penetrates the skin and can answer a number of other questions about possible skin absorption. (A. 61-64, 155-157.) A study of the type described (and now completed) by Dr. Maibach was "available" to OSHA

any time the Agency chose to obtain it. Unless OSHA is to be permitted to impose regulations based on "policy" rather than scientific information, the Agency will have to consider valid skin absorption data.

OSHA cannot shift to potentially regulated parties the Agency's own responsibility to obtain the kind of factual, scientific information the Act requires. This case well illustrates what can occur when an agency charged with developing standards based on "research, demonstrations, [and] experiments" promulgates regulations in disregard of available scientific research. OSHA's ban on dermal contact placed rubber companies in the position of having to seek out a university professor to conduct the very research study OSHA should have first obtained, to attempt to disprove the Agency's "policy". At rock bottom, OSHA has asked this Court to shift to regulated parties the task of developing data to disprove on factual grounds standards adopted by the Agency in reliance on "policy."

Respecting the dermal contact issue, this is a record-dependent case, resulting from OSHA's refusal to comply with the evidentiary requirements of the standard-setting sections of the Act. Based on its own careful review of *all* the evidence in the record, the court of appeals properly concluded that the dermal contact sections were not supported by substantial evidence and were not reasonably necessary. Under this Court's decision in *Universal Camera Corp.* v. *National Labor Relations Board*, 340 U.S. 474, 491 (1951), the Court should respect the effort of the court of appeals in reviewing all the portions of the factual record relating to the dermal contact provisions.

ARGUMENT

I. THE COURT OF APPEALS CORRECTLY HELD THAT THE DERMAL CONTACT SECTIONS OF THE BENZENE STANDARD WERE NOT "BASED UPON RESEARCH, DEMONSTRATIONS, [AND] EXPERIMENTS", AS REQUIRED BY THE ACT

A. The Statutory Framework For Standard-Setting And For Judicial Review Of Standards

This case arises procedurally under Section 6(f) of the Act, 29 U.S.C. § 655(f), which provides for judicial review of OSHA standards according to a "substantial evidence" test. Whether there is substantial evidence to support OSHA's action must be determined by reference to the specific requirements of the standard-setting provisions of the Act. The applicable sections of the Act are summarized below.

Section 6(f) of the Act provides that upon review of an OSHA standard by a court of appeals, "[t]he determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole." While courts of appeals have noted the "anomaly in subjecting notice and comment rulemaking . . . to the substantial evidence test" (*Associated Industries, Inc.* v. *Department of Labor*, 487 F.2d 342, 347 (2d Cir. 1973)),[29] they have also recognized that the substantial evidence test was the product of a conscious Congressional compromise. As Judge Friendly concluded after reviewing the legislative history of Section 6(f):

> [T]he intention to adopt the substantial evidence test for review as a tradeoff for the House's abandoning its insistence on rulemaking on the record, which would automatically have invoked that test under 5 U.S.C. § 706(2)(E), is apparent. (*Associated Industries, Inc.* v. *Department of Labor*, 487 F.2d 342, 349 (2d Cir. 1973).)[30]

[29] *Accord, Florida Peach Growers Ass'n* v. *Department of Labor*, 489 F.2d 120, 128 (5th Cir. 1974); *see also Industrial Union Department* v. *Hodgson*, 499 F.2d 467, 473 (D.C. Cir. 1974).

Upon review of a challenged OSHA standard, the Agency "has an affirmative burden to demonstrate the reasonableness of an adopted standard." (*Atlantic & Gulf Stevedores, Inc.* v. *Occupational Safety and Health Review Commission*, 534 F.2d 541, 551 (3d Cir. 1976).[31]

Because the Act prescribes different criteria for the adoption of different types of OSHA standards (such as emergency temporary standards or permanent standards), review of whether an OSHA standard is supported by substantial evidence must necessarily be conducted in the context of the specific standard at issue to "at a minimum determine if the Secretary applied the correct [criteria] . . . ." (*Synthetic Organic Chemical Mfrs.' Ass'n* v. *Brennan*, 503 F.2d 1155, 1160 (3d Cir. 1974).)

The specific standard-setting criteria applicable in this case are enumerated in Section 6(b)(5) of the Act, 29 U.S.C. § 655(b)(5), which mandates that OSHA set standards for toxic materials or harmful physical agents on the basis of the "best available evidence", "research, demonstrations, experiments, and such other information as may be appropriate", and "the latest available scientific data in the field." These specific requirements

[30] *Accord, Florida Peach Growers Ass'n* v. *Department of Labor*, 489 F.2d 120, 128 (5th Cir. 1974); *but cf. Industrial Union Department* v. *Hodgson*, 499 F.2d 467, 474-476 (D.C. Cir. 1974) (substantial evidence review for "factual" questions, a different and perhaps lesser review for "policy" issues).

A chronological summary of the legislative history of the standard-setting provisions of the Act is set forth in Addendum B to the API Brief. This discussion, and subsequent discussion of the legislative history, will refer to this Addendum.

The legislative history of Section 6(f) is described in the API Brief, Addendum B, especially at 7b, 12b, 20b-21b.

[31] *Accord, Associated Industries, Inc.* v. *Department of Labor*, 487 F.2d 342, 351-353 (2d Cir. 1973).

are supplemented by Section 3(8) of the Act, 29 U.S.C. § 652(8), applicable to all OSHA standards, which defines an "occupational safety and health standard" as one which is "reasonably necessary or appropriate to provide safe or healthful employment and places of employment." [32]

Judicial review of OSHA standards is aided by Section 6(e) of the Act, 29 U.S.C. § 655(e), which requires that whenever OSHA promulgates a standard, the Agency must publish an accompanying "statement of the reasons for such action . . . ." OSHA has fleshed out this provision in its own regulations, which provide that "the statement [of the basis and purpose of a standard] will show the significant issues which have been faced, and will articulate the rationale for their solution." (29 C.F.R. § 1911.18(b).)

Considered together, the foregoing statutory provisions evidence a clear Congressional directive that OSHA standards must be properly premised on a factual, scientific basis. Courts of appeals reviewing challenged OSHA standards have recognized this Congressional mandate. Even the D.C. Circuit, which has given the judicial review provisions an unduly restrictive interpretation when reviewing action by OSHA based on policy,[33] has required

[32] OSHA standards must also be consistent with general purpose of the Act, set forth in section 2(b), 29 U.S.C. § 651(b), "to assure *so far as possible* every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources." (Emphasis added.)

[33] *See supra*, at 21 n. 30. The D.C. Circuit in *Industrial Union Department* v. *Hodgson*, 499 F.2d 467, 474-476 (D.C. Cir. 1974), suggested that it was not applying a substantial evidence test on review of OSHA action based on "policy" grounds. The court offered no statutory basis for its decision, but rather supplied its own policy-based rationale, *i.e.*, that "policy choices of this sort are not susceptible to the same type of verification or refutation by reference to the record as are some factual questions." *Id.* at 475. The difficulty arises more with the court's misuse of this rationale than with the rationale itself. The court in the *IUD* case did not pay

OSHA's factual findings to be supported by evidence, not assumptions or pseudo-scientific speculation. In *Industrial Union Department* v. *Hodgson*, 499 F.2d 467 (D.C. Cir. 1974), the court noted that while some questions may be "on the frontiers of scientific knowledge" where "insufficient data is presently available",

> when the facts underlying the Secretary's determinations are susceptible to being found in the usual sense, that must be done, and the reviewing court will weigh them by the substantial evidence standard. (*Id.* at 474.)

Thus, even when the principal sections of a challenged OSHA standard have been upheld, other sections of the

sufficient heed to that part of the Congressional compromise which mandated detailed judicial review of all of OSHA's "determinations," however based.

Much OSHA "policy" is offered in lieu of factual evidence, as this case illustrates. The reviewing court should give close scrutiny to the record to insure that agency "policy" has not been misused in this way. In addition, the Agency should be required to identify the assumptions it made in adopting its "policy" and to specify the factual support at hand to support those assumptions. In reviewing the actions of other agencies, such as the Environmental Protection Agency, courts have required a comparable identification of assumptions and specification of bases, even where an "arbitrary and capricious" test was applicable on review. *See International Harvester Co.* v. *Ruckelshaus*, 478 F.2d 615, 643-45 (D.C. Cir. 1973); *Tanners' Council of America* v. *Train*, 540 F.2d 1188, 1192-94 (4th Cir. 1976). In *International Harvester* the D.C. Circuit itself explicitly stated that "[i]t is up to EPA, however, *to support its methodology as reliable*, and this *requires more than* reliance on the unknown, either by *speculation, or mere shifting back of the burden of proof*." 478 F.2d at 645 (emphasis added).

In short, while there is an element of truth in the D.C. Circuit's observations in the *IUD* case, that court there allowed itself to be carried too far in its resulting verbal formula for describing its review function regarding agency "policy". Its overstatement gives rise to the prospect that a reviewing court might not give OSHA's action the "close look" which the statute requires to be given. *Compare Florida Peach Growers Ass'n* v. *Department of Labor*, 489 F.2d 120, 129 (5th Cir. 1974); *Associated Industries, Inc.* v. *Department of Labor*, 487 F.2d 342, 351-353 (2d Cir. 1973).

standard have been set aside when the requisite factual findings had not been made.[34] This has occurred, for example, when the lack of factual support for a provision in a standard "may be partially attributable to the Secretary's failure to seek it." (*Id.* at 480.)

B. In Adopting The Dermal Contact Sections, OSHA Totally Ignored The Act's Mandate That Permanent Standards Shall Be Developed From Research, Demonstrations, And Experiments

In the face of the specific evidentiary requirements of Section 6(b)(5), OSHA has shown an evident lack of concern for addressing, much less resolving, factual and scientific questions relating to skin absorption of benzene from liquids containing trace amounts of this substance. Throughout the entire course of these proceedings, the issue of skin exposure has been merely a "side issue" to OSHA, which the Agency considered only as an adjunct to the airborne exposure provisions. Indeed the preamble to the benzene standard significantly fails to describe any demonstrated carcinogenic hazard associated with skin contact with liquids containing benzene. (*Compare* Pet. App. 78a-132a (health effects of inhalation).) Similarly, the preamble fails to identify any workplaces where significant skin contact with benzene arises. (*See* Pet. App. 192a-194a.)

In an apparent attempt to mask its own failure to obtain the type of information the statute requires, OSHA now presents this Court with the curious argument that the Act's requirement for "research, demonstrations, [and] experiments" is no requirement at all. Rather, OSHA asserts it has "discretion" to determine whether it is "appropriate" to gather factual information, and that the Agency's discretion is not reviewable under the

[34] *Industrial Union Department* v. *Hodgson*, 499 F.2d 467, 480-481 (D.C. Cir. 1974) (no finding was made respecting inter-industry differences in time needed for compliance).

Act's substantial evidence test, but should be set aside "only on the clearest abuse of discretion". (OSHA's Brief at 82.) Recourse to the language of the Act and its legislative history proves otherwise.[35]

1. *The substantial evidence test applies to all of OSHA's actions in setting standards under the Act.*

Respecting the appropriate standard of review, OSHA's assertions are directly contrary to the clear statement in Section 6(f) that OSHA's "determinations" are to be reviewed for substantial evidence.[36] There are no exceptions. Thus, in a standard-setting context, all of OSHA's determinations underlying the standard under review are subject to the substantial evidence test specified in Section 6(f), including determinations whether or not to seek additional factual data or information. To engraft an

[35] Thus, this is definitely not one of those relatively rare "circumstances when statutory language mandatory in form is [or should be] held to constitute a mere directory command to the agency, so that variance triggers no judicial sanction." *Alabama Power Co.* v. *Costle*, No. 78-1006, slip op. at 33 (D.C. Cir. June 18, 1979).

[36] Congress' action in prescribing a more-stringent-than-usual standard of review is a signal to reviewing courts of appeals not to gloss over problem areas.

More generally, as this Court said in a related context in *Addington* v. *Texas*, 47 U.S.L.W. 4473 (Apr. 30, 1979), a standard of proof has significance to a fact-finder:

> [E]ven if the particular standard-of-proof catchwords do not always make a great difference in a particular case, adopting a 'standard of proof is more than an empty semantic exercise.' *Tippitt* v. *Maryland*, 436 F.2d 1153, 1166 (CA4 1971) (Sobeloff, J., concurring and dissenting), cert. dismissed *sub nom. Murel* v. *Baltimore City Criminal Court*, 407 U.S. 355 (1972). 47 U.S.L.W. at 4475.

For the same reasons, the standard of review here is as important to the reviewing courts of appeals, to the Agency, and to those affected by OSHA's actions.

exception on the Act's judicial review provision would require judicial legislation. Not one jot of statutory language supports such an exception.

Of equal importance, the legislative history of the Act shows that adoption of the substantial evidence test was critical to the Congressional compromise that permitted passage of the Act.[37] Congress was quite concerned that it provide a meaningful judicial check on actions by an administrative agency it feared might establish standards lacking any significant scientific or factual basis.[38] OSHA understandably may not appreciate the value of such a check on its decisions, but Congress acted to provide a check among other things for the very reason OSHA here seeks to avoid it.[39]

2. *Section 6(b)(5) imposes evidentiary requirements for OSHA's permanent standards.*

Section 6(b)(5) states explicitly what is required of the Agency. It provides in part:

> Development of standards under this subsection *shall be* based upon research, demonstrations, experiments, and such other information as may be appropriate." (Emphasis added.)[40]

[37] *See supra*, at 20-21 & nn. 29-30; API Brief, Addendum B at 20b-21b.

[38] *See* API Brief, Addendum B at 6b-7b, 10b-12b, 19b-21b.

[39] The Assistant Secretary of Labor for Occupational Safety and Health, Eula Bingham, recently remarked that OSHA is not "prohibited from doing just about anything we want to do" to protect employees' safety and health, and further stated that adverse judicial decisions will not deter the Agency. Address by Assistant Secretary Bingham to ABA Institute on Law, Science and Technology in Health Risk Regulation (Apr. 20, 1979) reported at [1979] Occupational Safety & Health Reporter, Current Reports (BNA) at 1690. Given that view, perhaps it is not surprising that commentators have criticized the Agency's decisionmaking process. Those commentators have sought to have OSHA "isolate delicate scientific judgments from the rough and tumble of political pressure and the temptation to bend scientific testimony for regulatory expedience—a temptation that OSHA, together with other agencies, has already shown signs of succumbing to." FORTUNE, July 3, 1978, at 90.

This language of mandate is in sharp contrast to the discretionary authority given to OSHA later in the same section, to express standards in terms of objective criteria and desired performance "[w]henever practicable".

The Act's legislative history is equally clear that Congress intended in Section 6(b)(5) to impose specific evidentiary requirements on OSHA as part of the standard-setting process.[41] Special standard-setting criteria for occupational health standards were first proposed by the House Committee on Education and Labor (the "House Committee"), to take account of the somewhat different problems presented by occupational health hazards.[42] Un-

[40] The comma after the word "experiments" suggests that the phrase "as may be appropriate" was intended to modify only "such other information". OSHA's argument to the the contrary (OSHA's Brief at 82 n.67) is based only on a quotation from a report of the Senate Committee on Labor and Public Welfare. In its report, the Senate Committee stated its intention that standards promulgated under Section 6(b) be feasible requirements "which, where appropriate, shall be based on research, experiments, demonstrations, past experience, and the latest available scientific data." Subcomm. on Labor of the Senate Comm. on Labor and Public Welfare, 92d Cong., 1st Sess., *Legislative History Of The Occupational Safety And Health Act of 1970* (Comm. Print 1971), at 147 [hereinafter "Leg. Hist."]. The quoted language was part of a section-by-section summary of the major provisions of S.2193, which summary purported only to restate the provisions and not to interpret them. Under OSHA's argument, it would also have discretion as to whether to consider "past experience" and the "latest available scientific data", even though the text of Section 6(b)(5) is equally categorical as to consideration of those factors (*e.g.*, "[o]ther considerations *shall be* the latest available scientific data . . ." (emphasis added)).

[41] API Brief, Addendum B, 10b-11b.

[42] API Brief, Addendum B at 6b-7b, 10b-11b, 19b.

der the bill adopted by the House Committee, OSHA would have been allowed to set standards under informal notice-and-comment rulemaking procedures, "on the basis of the best available professional evidence." [43] Although adopted by the House Committee, this provision evoked bitter complaints from minority members of the Committee. In particular, the minority denounced the bill for allowing standards to be based on " 'views and arguments' rather than probative evidence",[44] and objected to the majority's rejection of formal rulemaking procedures for setting standards.[45]

The concerns of the House Committee minority were, however, heeded when the Senate Committee on Labor and Public Welfare (the "Senate Committee") considered S. 2193 in the fall of 1970. Although the Senate Committee had for the most part developed the bill independently, it specifically chose to follow the approach adopted by the House Committee of providing explicit criteria for setting health standards.[46] Furthermore, as part of key amendments obtained by minority members of the Senate Committee, a number of additional requirements were engrafted onto the House Committee's language. The added requirements emphasized the need for OSHA to develop scientific and factual bases for its standards. As redrafted by the Senate Committee, Section 6(b)(5) read as follows:

[43] Leg. Hist. 943; API Brief, Addendum B at 3b-5b. It was with respect to this early formulation of the standard-setting criteria of Section 6(b)(5) that the House Committee made the statement, on which OSHA so heavily relies (OSHA's Brief at 76), that "it is not intended that the Secretary be paralyzed by the debate surrounding diverse medical opinions." Leg. Hist. 848; API Brief, Addendum B at 6b n. 7.

[44] Leg. Hist. 884 (House Report, Additional Minority Views of Reps. Scherle *et al.*); API Brief, Addendum B at 6b-7b.

[45] Leg. Hist. 879.

[46] API Brief, Addendum B at 7b.

> The Secretary, in promulgating standards under this subsection, shall set the standard which most adequately *and feasibly* assures, on the basis of the best available [professional] evidence, that no employee will suffer any impairment of health or functional capacity, or diminished life expectancy even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. *Development of such standards shall be based on research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws.*[47]

These changes served several important purposes. By requiring that standards be "based upon research, demonstrations, experiments, and . . . other information", the Committee expressed its intent that OSHA develop scientifically-based, factually supported standards. The "research, demonstrations, [and] experiments" requirement thus represented an important substantive addition to the House Committee provision, which House minority members had objected would have allowed OSHA to issue standards based on "views and arguments". (*See supra*, at 28.)

The Senate Committee's amendment to Section 6(b)(5) focused attention on the central role of scientific research in the development of standards, and the Committee's intent that OSHA take full advantage of the latest avail-

[47] S.2193 (as reported) 91st Cong., 2d Sess. § 6(b)(5) (1970), Leg. Hist. 242 (new material indicated by italics; deleted material in brackets). The last sentence of the section, which is identical to the last sentence of the House Committee section, is not reproduced in the quoted text.

able data and scientific techniques. At the same time, there was no indication of concern that requiring OSHA to act on the basis of research and factual information would in any way "paralyze" the Agency.[48] To the contrary, the language of the amendment indicates the Senate Committee viewed the requirement that OSHA act on a scientific and factual basis as being wholly consistent with "the attainment of the highest degree of health and safety protection for the employee."

The Senate Committee's amendment emphasizing the need for scientific research in setting standards meshed with the "research" provisions which were already in the Committee bill. Those "research" provisions, which appeared in similar form in *every* occupational safety and health bill introduced in the 91st Congress,[49] directed the Secretary of Health, Education and Welfare to "conduct

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[48] The statement relied on by OSHA (OSHA's Brief at 76) and the IUD (IUD's Brief at 17)—that it was not intended that OSHA be "paralyzed" by medical debate (Leg. Hist. 848)—came in an early House Committee Report which was issued before the Senate Committee significantly amended the House Committee version of Section 6(b)(5). Notably, the House rejected the bill reported by its Committee. Moreover, the Senate Committee apparently disagreed with the House Committee regarding whether evidentiary requirements would paralyze OSHA's standard-setting efforts, because the Senate Committee added specific evidentiary requirements to its version of Section 6(b)(5), which reached well beyond the provision reported by the House Committee (Section 7(a)(4) of H.R. 16785, Leg. Hist. 943). Finally, and most importantly, the specific evidentiary requirements of Section 6(b)(5) were part of the Act as adopted by both Houses of Congress.

[49] *Every* occupational safety and health bill included in the Senate Committee print of the legislative history of the Act (*supra*, at 27 n. 40): (1) included as one of its specific purposes to provide for research in the field of occupational safety and health; (2) directed the Department of Health, Education and Welfare to conduct research; and (3) specifically authorized the Secretary of Labor to contract for research or other studies. S.2193 (as introduced), §§ 2(b)(3), 15, Leg. Hist. 2, 23-24; S.2788, §§ 2(b)(4), 17, Leg. Hist. 33, 63-65; S.4404, §§ 2(b)(5), 23, Leg. Hist. 75, 126-128; S.2193 (as reported), §§ 2(b)(2), 18, 19, Leg. Hist. 234, 274-282; S.2193 (as passed by Senate), §§ 2(b)(2), 19, 20, Leg. Hist. 530, 574-582; H.R. 843, §§ 2(b)(3), 15, Leg. Hist. 600, 621-623; H.R. 3809, §§ 2(b)(3), 15, Leg. Hist. 630, 651-652; H.R. 4294, §§ 2(b)(3), 15, Leg. Hist. 661, 672-673; H.R. 13373, §§ 2(b)(4), 17, Leg. Hist. 681, 711-713; H.R. 16785 (as introduced), §§ 2(b)(3), 19, Leg. Hist. 722-723, 753-757; H.R. 19200, §§ 2(b)(5), 23, Leg. Hist. 765, 816-818; H.R. 16785 (as reported), §§ 2(b)(3), 19, Leg. Hist. 832, 841-842; H.R. 16785 (as passed by House), §§ 2(b)(5), 23, Leg. Hist. 1092, 1107-1108.

. . . research, experiments, and demonstrations relating to occupational safety and health",[50] and created a new National Institute of Occupational Safety and Health ("NIOSH") to perform those functions.[51] A separate section of the Committee bill authorized the Secretary of Labor (OSHA) to enter into contracts with public or private organizations "for the purpose of conducting studies related to the establishing and applying of occupational safety and health standards . . . ." [52]

While the Senate Committee bill was the subject of debate and further modification by the full Senate, no change was made in the requirement that standards be developed "based upon research, demonstrations, [and] experiments".[53] And only a clarifying change was made in the "research" provisions of the bill.[54]

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[50] Leg. Hist. 274; *see id.* at 274-278.

[51] *Id.* at 279-282. NIOSH was established in the Department of Health, Education and Welfare ("HEW").

[52] S.2193 (as reported), 91st Cong., 2d Sess. § 18(b) (1970), Leg. Hist. 277; API Brief, Addendum B at 11b n. 15. Apparently in recognition that the research activities contracted for by OSHA might often be different from and supplementary to those of NIOSH, OSHA was directed to cooperate with HEW (of which NIOSH is part) "to avoid any duplication" of research efforts. *Id.*

[53] An amendment was adopted that left no doubt that the second and third sentences of Section 6(b)(5) apply to all permanent standards, including safety standards. The introductory phrase of the second sentence of Section 6(b)(5) was changed to refer to "standards under this subsection", *i.e.*, subsection (b) of Section 6, which prescribes how OSHA is to "promulgate . . . any occupational safety or health standard." Leg. Hist. 502; API Brief, Addendum B at 17b n. 18.

[54] Section 19(b)(2) of S.2193 (as passed by the Senate) was clarified to state that HEW should develop criteria "dealing with toxic materials and harmful physical agents . . . ." Leg. Hist. 575. The same language was added in the clarifying amendment to the first sentence of Section 6(b)(5). Leg. Hist. 538; API Brief, Addendum B at 16b-17b.

In the Senate-House Conference, the Senate provision, with its detailed criteria for setting standards dealing with toxic materials or harmful physical agents, was adopted, although the House prevailed in its insistence upon the stricter substantial evidence test for judicial review.[55] The Senate versions of the "research" provisions (Sections 20 and 22 of the Act) were also adopted.[56] The House prevailed with respect to its statement of the Act's purposes, which though consistent with the Senate statement of purposes, was "more detailed" [57] and emphasized more strongly the important role of research in the proper implementation of the Act.[58]

The picture that emerges from a review of the legislative history is that in Section 6(b)(5) Congress intended that OSHA would set standards based upon scientific evidence rather than "views and arguments".[59] The resulting specific statutory mandate that OSHA standards "shall be based upon research, demonstrations, [and] experiments" is directly contrary to OSHA's assertion

[55] API Brief, Addendum B at 20b-21b.

[56] Leg. Hist. 1174-1178, 1195-1196.

[57] Leg. Hist. 1185; API Brief, Addendum B at 20b n. 21.

[58] Those House provisions, now Sections 2(b)(5) and (6) of the Act, state that the overall purpose of the Act is to be achieved, *inter alia*, "by providing for research in the field of occupational safety and health" and "by exploring ways to discover latent diseases, establishing causal connections between diseases and work in environmental conditions, and conducting other research relating to health problems, in recognition of the fact that occupational health standards present problems often different from those involved in occupational safety".

The Conference Committee also adopted the broader House provision authorizing the Secretary (in Section 20(c) of the Act) to contract for studies relating to all of his responsibilities under the Act, rather than only with respect to his standard-setting responsibilities.

[59] Leg. Hist. 884. *See supra*, at 28, 29; API Brief, Addendum B at 6b-7b, 10b-11b.

that it has virtually unbridled discretion to determine whether it is "appropriate" to obtain factual information.[60] Moreover, Congress not only emphasized the importance of research activities to proper fulfillment of the Act's objectives,[61] but also provided OSHA itself with the means to obtain necessary factual information through the "research" provisions of the Act.[62]

3. *The record contains no significant scientific or factual basis for OSHA's dermal contact ban.*

OSHA's own statement of its reasons for the ban on dermal contact, recounted previously,[63] is startling for its lack of any significant scientific or factual basis. A provision of a standard which is based on "extremely limited" record evidence, "few studies" which are "not definitive", and OSHA's "policy" (Pet. App. 192a-193a) cannot be what Congress intended in Section 6(b)(5).[64] Yet OSHA nevertheless banned skin contact with liquids containing even trace amounts of benzene, thereby placing

[60] Even under OSHA's convoluted reading of the "research, demonstrations, [and] experiments" requirement, the Agency's determination not to obtain scientific data of the type suggested by Dr. Maibach and instead to regulate based on the scant information before it can hardly be described as "appropriate".

[61] Sections 2(b)(5) and (6) of the Act, 29 U.S.C. §§ 651 (b)(5), (6).

[62] Sections 20(a)(1), 20(c) and 22 of the Act, 29 U.S.C. §§ 669 (a)(1), (c), 671.

[63] *See supra*, at 7, 13.

[64] OSHA's stated basis for its ban on dermal contact fails even to live up to the Agency's own regulation requiring that any standard will be accompanied by a statement which "will show the significant issues which have been faced, and will articulate the rationale for their solution." 29 C.F.R. § 1911.18(b); *see supra*, at 22. OSHA standards have been set aside for failure to satisfy this requirement. *Dry Color Mfrs. Ass'n* v. *Department of Labor*, 486 F.2d 98 (3d Cir. 1973); *Associated Industries, Inc.* v. *Department of Labor*, 487 F.2d 342, 353 (2d Cir. 1973).

greater limitations on skin contact than on airborne exposures to benzene, even though the Agency recognized the only evidence of a carcinogenic hazard from benzene related to inhalation.[65]

From the outset, in proposing the benzene standard, OSHA candidly admitted that "studies indicate benzene is not readily absorbed through intact skin." [66] No significant contrary evidence regarding skin absorption was presented during the rulemaking proceeding on the standard.[67] Dr. Howard Maibach, Professor of Dermatology

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[65] An employer is exempt from many of the standard's requirements if workers' exposure to airborne concentrations does not exceed the "action level" of 0.5 ppm. *See* 29 C.F.R. §§ 1910.1028(b), (e)(3), Pet. App. 35a, 37a-38a. Rather than regulate consistently and provide an "action level" for dermal contact, OSHA banned skin contact completely. During the rulemaking proceeding on the amendments to the benzene standard, rubber companies urged adoption of such a "dermal action level" and provided evidence in support of such a provision. *See supra*, at 10-12 & nn. 18-20.

[66] 43 *Fed. Reg.* 27451, 27470 (May 27, 1977), Ex. 4.

[67] The only testimonial references in the record suggesting that benzene can be absorbed through the skin are found in cryptic remarks by two NIOSH witnesses. In response to a question as to whether they had "*any feeling* as to whether . . . dermal exposure is a contributing factor" (A. 40 (emphasis added)), the NIOSH witnesses stated that benzene can be absorbed through the skin. A. 40. As the court of appeals noted, however, "[e]xcept for a passing reference to what appears to be the 1961 positive study, these witnesses did not attempt to support their opinions by empirical data." Pet. App. 25a, 581 F.2d at 506.

These NIOSH witnesses apparently were even unaware of the existence of the reliable experimental technique of using radioactive-tagged benzene to measure definitively whether benzene penetrates the skin. Dr. Laigo of NIOSH testified:

> To what extent [benzene] would be absorbed in any particular exposure, you really don't know. *You can't measure that.* A. 40 (emphasis added).

The court of appeals thus properly determined that these remarks did not constitute evidence, let alone creditable evidence. Pet. App. 25a, 581 F.2d at 506.

at the University of California Medical Center, was the only witness participating in the original rulemaking proceeding [68] who reviewed in detail the state of scientific knowledge regarding skin absorption of benzene. (A. 58-77, 149-157.) Dr. Maibach concluded that:

> Admittedly, the overwhelming majority of the observations suggest that benzene does not penetrate the skin. One observation suggests it does. (A. 61.)

Dr. Maibach went on to say, however, that modern analytic techniques using radioactively-tagged Carbon-14 benzene can now provide conclusive answers regarding whether benzene is absorbed through the skin and the amount of any absorption. He stated:

> This is a simple technique. It has been done for over 100 organic compounds in the last decade, measuring the amount of transport to the skin, and it would tell us definitely, without argument, and efficiently, just how much of [sic—"if"] any benzene penetrates the skin. (A. 62.)

Dr. Maibach further testified that this experimental procedure could answer a number of other questions about possible skin absorption, that the necessary tests could be completed within six to twelve weeks, and that the tests could be done by anyone having the requisite analytic facilities for radioactively-tagged materials. (A. 61-64, 155-157.)

Dr. Maibach has now completed his skin absorption study. The results have been provided to OSHA.[69]

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[68] Dr. Maibach was called as a witness by the American Petroleum Institute.

[69] Dr. Maibach's study and results are set out in two technical reports, one dated January 19, 1979, and the other dated July 2, 1979. Dr. Maibach's first report was submitted to OSHA on January 22, 1979 and is reprinted as Appendix 1 to the rubber companies' Joint Memorandum in Opposition to the petitions for certiorari. Dr. Maibach's second report was furnished to OSHA on

OSHA to date apparently has not re-examined its ban on dermal contact in light of this careful study. Instead OSHA has attempted to resist application of the results of Dr. Maibach's study (at least insofar as set out in Dr. Maibach's first report) to the absorption issue in the benzene standard proceedings, and to argue that scientific information of the type provided by Dr. Maibach was not "available" at the time OSHA adopted or amended its standard. (*See* OSHA's Brief at 75-81.)

Dr. Maibach's study is itself not part of the record before this Court.[70] What *is in the record* is testimony in 1977 by Dr. Maibach regarding the nature of such a study, the information obtainable from it, and the time required for its completion (A. 61-64, 155-157), along with the added information, put before OSHA in 1978 at the time of the proceedings to amend the standard, that Dr. Maibach was actually going to carry out the study (Amend. Tr. 71-73).

Importantly, Dr. Maibach's study does not represent "one more study", and thus impliedly just a delaying

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July 9, 1979. A copy of the second report has been lodged with the Clerk in the event this Court should wish to have access to it.

In important part, Dr. Maibach's study found that only minute percentages of pure benzene or benzene contained in rubber solvents applied to the skin of rhesus monkeys were absorbed through the skin. This was so even with multiple doses approximating chronic exposures, and with "damaged" skin (*i.e.*, skin from which the *stratum corneum* had been completely removed).

Based on certain highly conservative assumptions, Dr. Maibach concluded that in passenger tire building the amount of benzene absorbed from skin contact with solvent containing benzene is a fraction of the amount of benzene permitted to be inhaled at 1 ppm. *See also supra*, at 12 n. 20 (referring to Dr. Johnson's comparative study of routes of possible exposure, relying on Dr. Maibach's work for the dermal aspect of the comparison).

[70] For that reason rubber companies do not here respond to OSHA's asserted deficiencies in Dr. Maibach's study. Rubber companies do not, however, agree with OSHA's assertions, and will respond to them at such time as OSHA actually considers on the merits the issue of skin absorption of benzene and liquids containing small amounts of benzene.

tactic by parties about to be subjected to government regulation, as OSHA would have this Court believe. (*See* OSHA's Brief at 81.) Rather, Dr. Maibach's work now constitutes the only valid skin absorption study of benzene in OSHA's possession. OSHA did not have any significant scientific data relating to skin absorption of benzene when it proposed the benzene standard in 1977, and, apart from Dr. Maibach's study, it has not generated or received any such data since that time. Unless this Court sanctions OSHA's imposition of regulations based on a fact-bereft "policy" rather than upon scientific information, the Agency will have to consider Dr. Maibach's absorption study.

OSHA's argument that Dr. Maibach's study was not available to it is equally without merit.[71] The "unrefuted testimony" during the hearings on the original proposed standard is that anyone with the analytic facilities available could have completed the tests in six to twelve weeks. (Pet. App. 26a-27a, 581 F.2d at 507, 508.) When in the hearings in the proceedings to amend the standard, the rubber companies reported that Dr. Maibach was then going forward with the study, the Director of OSHA's Health Standards Programs again stated that the Agency would act in the absence of the study's results. (A. 185.)

The benzene standard has never gone into effect. Because of this circumstance, the rubber companies did not press Dr. Maibach to complete the study within the six-to-twelve week period he testified would be needed for the study. Instead, Dr. Maibach has conducted his experiments without reference to a time objective. The experiments comprising the study were accomplished with first priority given to his teaching schedule and other research projects. Nonetheless, the total elapsed working time actually spent in conducting Dr. Maibach's experiments has been less than twelve weeks. Of course, of greater importance now is the circumstance that the absorption data actually has been obtained.

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[71] Again, OSHA could consider the study now, if it chose to do so.

4. *OSHA cannot shift to regulated parties the task of developing data to disprove on factual grounds standards adopted in reliance on "policy".*

OSHA cannot shift to regulated parties its own responsibility to obtain the kind of information the statute requires. (*See* OSHA's Brief at 77 n. 61.) Section 6(b)(5) requires *the Agency* to act on the basis of "research, demonstrations, [and] experiments", and the Act's "research" provisions give OSHA the means of doing so. Scientific evidence relating to skin absorption was available any time OSHA chose to obtain it. OSHA has represented to this Court that it has "a substantial scientific staff and a decade's experience in the administration of toxic substances regulation" (OSHA's Brief at 66-67), and also that "questions concerning the extent of absorption of benzene into the body through exposed surfaces were *obvious candidates* for research." (OSHA's Brief at 77 n. 61 (emphasis added).) Given OSHA's conceded lack of evidence respecting skin absorption (*see supra*, at 7, 33-34), the Agency should have obtained scientific information on this issue prior to proposing the dermal portions of the standard. OSHA could have gathered the data either through use of NIOSH's extensive research capabilities,[72] or by contracting with scientists or research organizations.[73]

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[72] Section 20(a)(1) of the Act, 29 U.S.C. § 669(a)(1), provides that "[t]he Secretary of Health, Education and Welfare, *after consultation with the Secretary [of Labor]*, . . . shall conduct (directly or by grants or contracts) *research, experiments and demonstrations relating to occupational safety and health* . . ." (emphasis added). NIOSH is generally to perform these and other functions of the Secretary of Health, Education and Welfare under the Act. 29 U.S.C. §§ 669(e), 671(a). The general scope of NIOSH's activities is set forth in 29 U.S.C. §§ 669, 671.

[73] OSHA has not hesitated to use outside consultants when it suits the Agency's purposes. For example, in the hearing in the original benzene prcoeeding, OSHA called various scientific witnesses, as well as NIOSH witnesses, to present new evidence and to review existing scientific evidence relating to the airborne exposure provisions of

At a minimum, OSHA could have given industry adequate notice of the Agency's intention to ban dermal contact with liquids containing even trace amounts of benzene, so that affected parties such as the rubber companies could have conducted skin absorption studies.[74] In any event, OSHA was explicitly informed both of the outdated and inconclusive nature of its existing data and of the availability of reliable experimental techniques to obtain needed data when Dr. Maibach testified before the

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the standard. Had it chosen to do so, the Agency could have contracted for a review of scientific methods relating to skin absorption, so that it would have been aware of the straightforward and reliable research techniques as to which Dr. Maibach testified.

In a subsequent proceeding (Identification, Classification and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk, 42 *Fed. Reg.* 54147-54247, Oct. 4, 1977), OSHA contracted with numerous scientific witnesses, at a cost of many thousands of dollars, to present scientific evidence (including voluminous literature citations) relating to specific provisions of its proposal. In the same proceeding, OSHA engaged an outside contractor to review and advise the Agency on a wide variety of scientific, economic and other technical aspects of the proposal. It has been reported that OSHA had paid that contractor "close to $400,000" as of November 1978. 88 Cong. Rec. H5417 (daily ed. June 28, 1979).

[74] As described in rubber companies' Joint Memorandum in Opposition to the petitions for certiorari (at 9-12, 26-30), and as discussed in detail in rubber companies' brief filed with the court of appeals (Joint Brief for Rubber Companies, *et al.* (May 8, 1978), at 4-8, 12-15, Amend. Ex. 96), both the ETS and the proposed standard included a "percentage exclusion" totally exempting from the standard's coverage materials with less than a specified benzene content. *See supra*, at 5-6 & n. 10. When OSHA issued its original standard covering any material with any benzene content, in contrast to its previous position and without any express notice, its action came as a surprise, at least to rubber companies.

OSHA admits to having been put on notice by rubber companies in the original rulemaking proceeding that the dermal contact provisions were "overly restrictive", "impractical", and "burdensome and disruptive of the manufacturing process." Brief for the Secretary of Labor (before the court of appeals) (June 1978), at 100 n. 93.

Agency on August 3, 1977. (A. 58-77, 149-157.)[75] OSHA could easily have arranged for the necessary experiments to be completed in the six months which elapsed before the standard was promulgated in February, 1978.

OSHA unblushingly now argues that the passage of the Act in 1970 should have put rubber companies on notice that the Agency would act as it did in 1978. OSHA asserts:

> The statute itself put industry on notice that toxic substances are subject to regulation, and it was common knowledge that benzene is toxic. . . . Industry could have begun the process of research [relating to skin contact with benzene] as soon as the statute was enacted; it did not need to wait until the initial notice of rulemaking. (OSHA's Brief at 77 n. 61.)

OSHA's argument *could be* correct only if rubber companies and others *in 1970* could have foreseen: that OSHA would in 1977 select benzene from among the more than 26,000 toxic substances[76] as a candidate for further regulation; that after proposing an exemption for mixtures containing small amounts of benzene, OSHA would in its final standard prohibit all skin contact with mixtures containing any amount of benzene; that OSHA's ban on

[75] OSHA presumably was aware before 1977 of the reliable experimental technique of using materials "labeled" with radioactive carbon (^{14}C). The Assistant Secretary of Labor for OSHA, Dr. Eula Bingham, reported in 1974 on an experiment in which ^{14}C-labeled benzo[a]pyrene (BaP) was used. R. W. Niemeier and E. Bingham, *Distribution of Metabolites of Benzo[a]pyrene in the Isolated Perfused Rabbit Lung Preparation*, 29(1) Toxicol. Appl. Pharmacol. 93-94 (1974) (abstract).

[76] I NIOSH, REGISTRY OF TOXIC EFFECTS OF CHEMICAL SUBSTANCES xiii (1977 ed., Sept. 1977) (26,478 toxic chemical compounds). NIOSH has published a list of 2,415 potential occupational carcinogens, of which 1,905 substances "were selected on the basis of reported neoplastic or carcinogenic effects." NIOSH, SUSPECTED CARCINOGENS: A SUBFILE OF TOXIC EFFECTS OF CHEMICAL SUBSTANCES, foreward (2d ed. Dec. 1976).

dermal contact would be adopted based on OSHA's "policy" and without any significant factual support; and that after banning dermal contact, OSHA would persist in disregarding available research data relating to skin absorption. Although OSHA may consider the passage of the Act to be sufficient "notice" of the Agency's intentions, the statute requires evidence, not this type of "notice," to support standards.

Given the explicit testimony and comment received by the Agency during its administrative proceedings, OSHA cannot support its decision to regulate dermal contact in ignorance of scientific information of the type the Act both *requires* and *enables* the Agency to obtain. An agency charged with developing standards on the basis of "research, demonstrations, [and] experiments" must consider available scientific research. As a general matter, OSHA, prior to proposing standards, should evaluate initially whether factual evidence and research data in its possession are sufficient to support its contemplated regulatory action, whether gaps exist in this information, and whether other data are readily available to fill any gaps in information and to confirm or deny such information. Where, as here, scientific research can promptly fill informational gaps, the requisite research studies can readily be obtained.[77]

OSHA itself has recognized the need to follow such a scientific approach; the Agency's proposed generic carcinogen standard would permit OSHA to delay for up to 180 days publication of information relating to the classification of a toxic substance where:

[77] Other cases may pose different issues, especially where the research or experiments cannot be carried out within such a short time. This case does not, for example, raise the same issues which would arise where the needed data or information cannot be obtained without work over 12-18 months or even several years. Presumably where OSHA faces such a situation it must weigh factors such as the immediacy of need for regulatory action and the importance to the regulatory situation of the information.

> information exists that additional scientific data or study that may be relevant to the classification of a toxic substance is not immediately available or does not yet exist but will be available within a short period of time. (42 Fed. Reg. 54147, 54184 (Oct. 4, 1977).)[78]

The use by other scientific regulatory agencies of outside research facilities and consultants to obtain needed scientific data is widespread.

Nonetheless, as Judge Bazelon recently observed, "if there is no commitment to a candid exploration of the issues, the predicate for good decisionmaking will be lacking."[79] Judge Bazelon's observation aptly describes OSHA's action in this case. Relying on its "policy" (Pet. App. 192a), the Agency promulgated a ban on dermal contact "which would require an established industry to change long-followed work practices that are not demonstrably unsafe." (Pet. App. 27a, 581 F.2d at 508.) Rubber companies were placed in the position of having had to seek out a university professor to conduct the very research studies OSHA should have first obtained, in order to attempt to disprove the Agency's "policy". Where the burden of supporting its standards by substantial

[78] This 180-day period proposed by OSHA provided the time period for the hypothetical question posed to OSHA's Director of Health Standards Programs during the hearing on the amendment to the benzene standard. That question was whether OSHA would change its projected timetable for adopting the amendment if the results of a skin absorption study of the type being conducted by Dr. Maibach "could be made available to OSHA within 180 days". A. 184-185. OSHA's Director responded: "No, sir." A. 185; *see supra*, at 10. Contrary to OSHA's assertion, rubber companies did not request OSHA "to reopen the record and stay the standard for 180 days . . . ." OSHA's Brief at 77 n. 61. Indeed, the benzene standard had previously been stayed by the court of appeals. *See supra*, at 9 n. 13.

[79] "Risk and Responsibility", Address by Circuit Judge David L. Bazelon, ABA National Institute on Law, Science and Technology in Health Risk Regulation, ABA Section of Science and Technology (Apr. 20, 1979), at 12, reprinted in SCIENCE, July 20, 1979, at 280.

evidence has been placed with OSHA, industry parties should not be "confronted with the often-formidable task of establishing a 'negative averment'." (*International Harvester Co.* v. *Ruckelshaus*, 478 F.2d 615, 643 (D.C. Cir. 1973) (quoting *United States* v. *Denver & Rio Grande R.R.*, 191 U.S. 84, 92 (1903).)

C. OSHA Cannot Now Justify Its Ban On Dermal Contact By Post Hoc Rationalizations

Faced with the findings of the court below that its ban on dermal contact was neither supported by substantial evidence, as required by Section 6(f) of the Act, 29 U.S.C. § 655(f), nor "reasonably necessary" within the meaning of Section 3(8) of the Act, 29 U.S.C. § 652(8), OSHA's Brief attempts to provide new explanations of the reasons for the Agency's action. (OSHA's Brief at 27-28.) The explanations by OSHA's lawyers, advanced for the first time before the court of appeals[80] carry no weight:

> It has long been settled that in reviewing an agency action and the adequacy of an agency's articulation of its action, including findings of fact and reasoning processes, courts must look to the record that was considered by the agency and to the factual findings and reasoning of the agency—not to *post hoc* rationalizations of counsel or even agency members . . . ." (*Dry Color Mfrs.' Ass'n* v. *Department of Labor*, 486 F.2d 98, 104 n.8 (3d Cir. 1973).)[81]

[80] Similar assertions as to the basis for OSHA's action first appeared in OSHA's briefs to the court of appeals. They were reiterated and embellished in OSHA's Reply Memorandum in support of its petition for certiorari. Reply Memorandum for Petitioner in No. 78-1036, Feb. 1979, at 4-5.

[81] *See supra*, at 15-16 & n. 26. As stated in *Vermont Yankee Nuclear Power Corp.* v. *Natural Resources Defense Council*, 435 U.S. 519, 549 (1978), this Court has:

> made it abundantly clear before that when there is a contemporaneous explanation of the agency decision, the validity of that action must "stand or fall on the propriety of that finding, judged, of course, by the appropriate standard of review. If that finding is not sustainable on the administrative record

The court of appeals followed this principle and on the basis of *all* the evidence in the record set aside the dermal contact sections. The court below specifically rejected as a "post hoc rationalization" OSHA's attempt to justify the dermal contact sections out of a concern for dermatitis.[82] This Court should similarly reject OSHA's eleventh-hour attempt to "bootstrap" support for its action.[83]

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made, then the [agency's] decision must be vacated and the matter remanded [to the agency] for further consideration." *Camp* v. *Pitts*, 411 U.S. 138, 143 (1973). See also *SEC* v. *Chenery Corp.*, 318 U.S. 80 (1943).

[82] OSHA persists in arguing to this Court that the dermal contact sections were based on a concern for dermatitis. OSHA's Brief at 28, 82-83 n. 67. Even if that were the case, as the court of appeals specifically found it was not (Pet. App. 22a-23a, 581 F.2d at 505-506), exposure limits of a regulation developed to protect against cancer are a grossly inappropriate method for dealing with dermatitis. A concern for dermatitis cannot reasonably support a requirement that all containers containing any amount of benzene be labeled as a "CANCER HAZARD". *See* 29 C.F.R. § 1910.1028(b), (c)(2), and (k)(2)-(4), Pet. App. 35a-36a, 42a, 47a-48a, and *supra*, at 6 n. 11. The record contains little evidence respecting a risk of dermatitis. More importantly, however, *after* OSHA issued the benzene standard the Agency formed an advisory committee to deal directly with problems of skin hazards, including dermatitis. On March 14, 1978, OSHA announced formation of an ad hoc advisory committee to "identify the occupational exposures in industry which pose a hazard to the skin and/or use of the skin as a portal of entry" and to "provide OSHA with a set of guidelines to use in the drafting of a proposed standard on cutaneous hazards". 43 *Fed. Reg.* 10647-10648 (Mar. 14, 1978).

[83] OSHA's newly proferred justifications for its ban on dermal contact seriously overstate the record evidence in a number of respects. Several examples suffice.

Quoting the one study in the record that found any skin absorption of benzene, OSHA asserts that "the view is generally accepted that [benzene] has the ability to be absorbed through the skin . . . ." OSHA's Brief at 27. However, the sentence being quoted from the study continues:

> *but to an extent which does not induce intoxication. It is also accepted in practice that the sole essential path of benzene absorption under industrial conditions is the lungs.* A. 107 (emphasis added).

That study, which OSHA admits is not "definitive" (OSHA's Brief at 27 n. 29), and whose methodological deficiencies were discussed in detail by Dr. Maibach (A. 60-61, 152-155), concluded in 1961 only that "the absorption of benzene throughout [sic] the skin must not be neglected." A. 120. As the court of appeals observed, "the 1961 study reporting positive results used a technique, compressing benzene-soaked cotton against the skin with a glass plate for prolonged periods, that is recognized today as an efficient way to drive molecules into the skin." Pet. App. 24a, 581 F.2d at 506.

OSHA asserts that "[e]xperiments show skin absorption of benzene in animals", citing, among other things, a study in the record (Ex. 2-46 at 1-2, A. 95-96). OSHA's Brief at 27. OSHA's reference is to the introductory section of that study, in which the authors review earlier (pre-1955) studies. The study itself (Ex. 2-46) concludes that the "possibility of a percutaneous passage of benzene in the experimental conditions adopted is therefore *rejected*." A. 100 (emphasis added).

OSHA speculates that benzene "*may* be absorbed through damaged skin" (OSHA's Brief at 27 (emphasis added)), quoting Dr. Maibach's testimony that it is "ordinarily assumed that penetration of any molecule will be greater through damaged skin . . . ." A. 64-65. In the same sentence, Dr. Maibach went on to say:

> *but unfortunately I have to tell you that today that is usually as [sic] assumption rather than a fact, . . . we have almost no background data to verify that assumption, and it could be that when we get the data, it may be very surprising.* A. 64 (emphasis added).

OSHA represents to this Court that where benzene is present in solvents, the solvents can "result in or increase the extent of skin absorption of benzene." OSHA's Brief at 28. OSHA cites as authority its own preamble to the benzene standard, which contains an unsupported statement to the same effect. Contrary to OSHA's statement, Dr. Maibach's first report, which was submitted to OSHA in January 1979, found that proportionally *less* benzene was absorbed when contained in rubber solvent than when 100 percent benzene was used. Rubber companies' Joint Memorandum in Opposition to the petitions for certiorari (Jan. 26, 1979), App. 1 at 9a.

OSHA states it is "advisable to guard against dermal contact in order to [facilitate compliance with the airborne exposure provisions]." OSHA's Brief at 28. Even at this late date, OSHA persists in its focus on airborne exposure, failing to recognize that even despite compliance by rubber companies with airborne exposure limits, they cannot avoid dermal contact in their operations.

II. THIS COURT SHOULD NOT DISTURB THE COURT OF APPEALS' FINDINGS THAT THE DERMAL CONTACT SECTIONS WERE NOT SUPPORTED BY SUBSTANTIAL EVIDENCE AND WERE NOT REASONABLY NECESSARY

Respecting the dermal contact sections, this is a record-dependent case, relating to OSHA's failure to comply with the evidentiary portions of the standard-setting provisions of the Act. Recognizing that whether there was substantial evidence supporting the dermal contact sections could be determined only on the basis of the particular facts shown on the record before it, the court of appeals conducted a careful and thorough review of the record (Pet. App. 22a-27a, 581 F.2d at 505-508), consistent with its statutory obligation to review closely OSHA's actions. Based on all the evidence in the record, the court below properly concluded that the dermal contact sections were not supported by substantial evidence and were not reasonably necessary.

As this Court stated in *Universal Camera Corp.* v. *National Labor Relations Board*:

> Whether on the record as a whole there is substantial evidence to support agency findings is a question which Congress has placed in the keeping of the Courts of Appeals. This Court will intervene only in what ought to be the rare instance when the standard appears to have been misapprehended or grossly misapplied. (*Universal Camera Corp.* v. *National Labor Relations Board*, 340 U.S. 474, 491 (1951).)[84]

[84] *Accord, Mobil Oil Corp.* v. *Federal Power Commission*, 417 U.S. 283 (1974); *Central Hardware* v. *National Labor Relations Board*, 407 U.S. 539 (1972); *see also National Labor Relations Board* v. *Baptist Hospital, Inc.*, 47 U.S.L.W. 4789, 4791-4793 (opinion of the Court) and 4794 (Brennan, J., concurring in the judgment) (June 20, 1979).

OSHA has not "met its burden of demonstrating that the Court of Appeals misapprehended or grossly misapplied the substantial evidence standard" (*Mobil Oil Corp.* v. *Federal Power Commission*, 417 U.S. 283, 330 (1974)), and thus this Court should respect the effort of the court of appeals in going through all the portions of the factual record relating to the dermal contact provisions.[85]

CONCLUSION

For the foregoing reasons, the judgment of the court of appeals respecting the dermal contact sections should be affirmed.[86]

Respectfully submitted,

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July 30, 1979

[85] If, however, this Court does choose to take on that task and duplicate it, the result should remain the same.

[86] If this Court should determine not to affirm the court of appeals' judgment respecting the dermal contact sections, the case should be remanded to the court of appeals among other things for consideration of the feasibility of the requirements of these sections, an issue which the court below did not reach. *See supra*, at 16.

FOR ARGUMENT

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In the Supreme Court of the United States

OCTOBER TERM, 1979

INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
PETITIONER

v.

AMERICAN PETROLEUM INSTITUTE, ET AL.

RAY MARSHALL, SECRETARY OF LABOR, PETITIONER

v.

AMERICAN PETROLEUM INSTITUTE, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

REPLY BRIEF FOR THE FEDERAL PARTIES

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1. The court of appeals held that the Secretary may promulgate an OSHA standard under 29 U.S.C. 655(b) only where he demonstrates that the standard

will produce "measurable" or "quantifiable" health benefits (*i.e.*, lives saved), and, after quantifying the health benefits, the Secretary demonstrates that they "bear a reasonable relationship" to the standard's cost. Where the Secretary is unable to demonstrate quantifiable benefits because the epidemiological data are too incomplete to permit reliable estimates, no standard at all may issue even where the Secretary draws the *qualitative* conclusion, based on experience and expert opinion, that the standard will provide an appreciable measure of occupational health protection (Pet. App. 17a-21a n.23, 24a).

Although respondents support the holding below, they also urge affirmance on the narrower theory that no OSHA standard may be issued where the Secretary does not "consider" "educated estimates" of health benefits from reduced exposure, at least where, as respondents contend is true here, such estimates are possible (API Br. 21-24, 27, 29, 33, 43, 69-70, 73-75) and the standard will require an expenditure of "enormous resources to prevent a *de minimis* health risk" (*id.* at 25, 29, 31-35, 36-41, 81 n.121). The factual premises from which this argument proceeds, however, are foreclosed by the Secretary's findings based on substantial evidence.

a. The Secretary "considered" extensive evidence on both sides of the question of whether sufficiently accurate exposure data existed to permit a reliable risk assessment for long-term, low-level

exposure to benzene, and he explained why, in his judgment, such extrapolations are not possible for benzene based on existing data (see Pet. App. 96a, 112a-115a, 117a, 125a, 132a, 160a, 182a-185a; and our opening brief at pages 63-69)[1] The Secretary's finding, resting as it does on substantial evidence, is "conclusive," 29 U.S.C. 655(f), and forecloses respondents' contrary assertion.

Respondents seek to discredit the Secretary's conclusions with the argument that a physicist who testified for respondents (Dr. Wilson) was able to prepare an "upper-bound" risk assessment for benzene. This risk assessment, respondents claim (API Br. 20-21), demonstrates that, at most, only two cancers would be saved every six years by the benzene standard. Respondents claim that Dr. Wilson avoided the pitfalls of the unknown by employing "conservative" assumptions for every unknown factor or relationship and thus obtained an "upper bound" estimate of the maximum possible health benefits (that is, the health

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[1] See Tr. 30, 152, 287-288, 352, 359, 363-364, 401-402, 414, 417, 746, 761, 777, 895, 925, 1053, 1067, 1178-1189, 1210, 1214-1215, 1227, 1229, 1327, 2500, 2520-2521; Exhs. 17 at 7, 149-D at 15, 2.B-272 at 1; see also the Secretary's preamble to the coke ovens standard on this issue (41 Fed. Reg. 46742 (1976)), incorporated by reference in the benzene preamble (Pet. App. 163a). The court of appeals agreed with the Secretary's conclusion but speculated that such risk assessments would be possible in the future (Pet. App. 18a-19a n.23, 21a, 23a). Contrary to respondents' assertions (API Br. 73-74, 76-78), the court did not hold that a risk assessment like Dr. Wilson's would have satisfied its test.

benefits could not be more, but could be less, than two lives saved every six years).

In fact, as we show in Appendix A, *infra*, Dr. Wilson did not employ "conservative" assumptions. For example, although respondents claim (API Br. 76, 80 n.119) that Dr. Wilson based his demonstration on the Infante data, he did no such thing. To the contrary, Dr. Wilson apparently decided (A. 171) that application of his predetermined mathematical model (a straight line on a graph) to the Infante data would result in too great an excess risk, and he inexplicably drew a line in his diagram (*ibid.*) at an *assumed* risk many times lower than that indicated by the Infante data.[2] In Appendix A, we have itemized these and other assumptions made by Dr. Wilson. We also show that by using different and "conservative" assumptions, the Secretary's benzene standard will save 1380 leukemias every five years—800 times the number obtained by Dr. Wilson. We do not contend that the latter estimate is any more valid than

[2] Indeed, Dr. Wilson's assumed risk line is many times lower than that indicated by the Infante data, even if the Infante data reflect average exposures at 100 ppm, as respondents claim (API Br. 12-14). In this connection, respondents are less than frank in their assertion (API Br. 80 n.119) that "[w]hat OSHA fails to disclose (if, indeed, it ever considered comparing Infante's and Wilson's results) is that Infante's findings are equivalent to slightly *less* than 2 cases every six years" and that "Dr. Wilson reached approximately the same result in applying the Infante data * * *." As stated above, Dr. Wilson did *not* extrapolate from the Infante data, and it is not clear from his testimony, statement or diagram (see A. 170-171) that he extrapolated from any data at all.

Dr. Wilson's. Our point is that the severe incompleteness of epidemiological data for benzene, combined with the uncertainty inherent in such exercises, precludes any meaningful use of even an "upper bound" risk assessment for purposes of setting an occupational health standard for benzene.[3]

[3] Respondents' contention (API Br. 22-23) that the Secretary's preamble did not give a "coherent and rational" rejection of Dr. Wilson's views and arguments is wrong. The preamble discusses throughout the large number of uncertainties that prevent useful risk quantification for the benzene standard (see Pet. App. 96a, 112a-115a, 117a, 125a, 160a-161a, 182a-185a). No more detailed response was required. See *Bowman Transportation, Inc.* v. *Arkansas-Best Freight System, Inc.*, 419 U.S. 281, 291 (1974); 29 U.S.C. 655(b)(8), 655(e).

That the Secretary and other agencies have found risk assessment to be a useful administrative tool for estimating the excess risk posed by substances *other* than benzene lends no support to respondents' factual claim that the technique is equally useful in predicting the risks associated with long-term, low-level exposures to benzene. The utility of the methodology obviously depends upon the quality of the data, the number of assumptions that must be made, and the degree of precision needed in a particular case. Respondents simply refuse to accept the fact, supported by substantial evidence, that, however precise the data may be for other substances and uses, the best available data for *benzene* are too imprecise to provide useful results for predicting risk for long-term low-level occupational exposure to that substance. Respondents' reliance on a preliminary risk assessment concerning benzene prepared by a group at EPA is misplaced (A. 14-29). Appendix A illustrates why this report is inconsistent with Dr. Wilson's estimates, and why, as EPA itself concluded, its estimates could be in error by "several orders of magnitude" (A. 25). For the view that there is no such thing as a "conservative" upper bound risk assessment, due to the inability to identify truly conservative assumptions, see Cornfield, *Carcinogenic Risk Assessments*, 198 Science 693, 695-696 (1977).

b. Respondents contend (API Br. 13-17, 30, 32, 81 n.121) that "uncontradicted evidence" in the record shows that the risk of leukemia at lifelong exposures to benzene at 10 ppm is *de minimis*," "insignificant," "exceedingly small," and "miniscule." As we have already mentioned, however, the Secretary specifically found that the risk could not be quantified or usefully approximated based on currently available evidence and that, based on present knowledge, no level of exposure could be considered safe. In light of that finding, which is supported by substantial evidence, there is no merit to respondents' argument that the record affirmatively shows that the excess risk of cancer at existing levels of exposure is "*de minimis*."[4]

Respondents' contrary claim rests on misinterpretation of the "positive" studies and blind fidelity to discredited "negative" studies. To begin with, respondents' suggestion (API Br. 8) that "none" of

[4] The court of appeals expressly upheld the Secretary's determination that low levels of exposure to benzene pose a cancer risk and held only that the Secretary had not been able to adduce substantial evidence as to "the extent of" that risk (Pet. App. 18a-19a). Thus, the court concluded not that the benefits of the new benzene standard *were* insignificant, but that the Secretary had failed to submit "empirical evidence" showing that the risk of not adopting that standard *was not* insignificant (*ibid.*). Nor did the court below hold that the benefits could be estimated. To the contrary, the court stated that "valid extrapolations *will be* possible as more is known about the effects of past exposure at higher levels" and that the Secretary's conclusion that such extrapolations were now "impossible" "may be correct" (*id.* at 19a-21a & n.23) (emphasis added)).

the positive studies showed a risk below 100 ppm ignores the fact that a study based on data at a given exposure level showing an excess risk at such level cannot negate the existence of an excess risk at any lower level. In addition, respondents inaccurately assert that the levels of exposure in the Ohio plants studied by Dr. Infante averaged approximately 100 ppm and ranged as high as 1000 ppm (API Br. 12-13). Consequently, respondents conclude that Dr. Infante found an excess risk of leukemia only because the exposure levels averaged at least above 100 ppm. In fact, however, a 1946 report of the Industrial Commission of Ohio (Pet. App. 105a) shows that the exposure levels in the plants ranged "in most instances" from "0 to 10 to 15 parts per million," thus suggesting that the study indeed reflected the excess risk at low levels of exposure.[5] On the other hand, some evidence does suggest that exposure levels at the plants may have been higher (*ibid.*). The Secretary drew the factual determination that "[b]ecause of the lack of definitive exposure data, OSHA cannot derive

[5] Moreover, epidemiological evidence concerning benzene does indicate an excess health risk at low levels. For example, three Dow Chemical workers who died from leukemia had been exposed to benzene concentrations of 2 to 9 ppm. The expected number of "normal" leukemias in this population was 0.8 (Exh. 154 at 10; see Pet. App. 108a-110a). However, the total number of leukemias found in the study, albeit higher than the normal rate, was not statistically significant. (See also Tr. 753-754.) In addition, another study (Tr. 148) reported chromosomal damage at benzene exposure levels of 5 to 25 ppm has been observed (Tr. 148; Exh. 5A at 3-3). Nonmalignant blood disorders have been observed at 10 to 20 ppm (Tr. 360-361).

any conclusions linking the excess leukemia risk observed [by Dr. Infante] with any specific exposure level" (*ibid.*). Substantial evidence supported the Secretary's conclusion that the actual Ohio exposure levels studied by Infante could *not* be determined. This finding forecloses respondents' claim that the levels studied by Dr. Infante averaged 100 ppm or more.[6]

Respondents also contend (API Br. 14) that the three principal positive studies demonstrate that "when benzene exposures were reduced below 100 ppm—*but not eliminated*—the excess incidence of

[6] In this connection, respondents dispute (API Br. 11 n.19) that the additional leukemia deaths found by Dr. Sakol among the pliofilm workers studied by Dr. Infante show an even greater risk than that found by Dr. Infante. Respondents argue that Dr. Infante stated that these cases were *not* in his study and that, in any event, the study population would have to be enlarged if these cases were added. Dr. Infante testified, however, that Dr. Sakol's patients, or at least some of them, were in his cohort (Tr. 768-769, 1198-1199), but that the additional cases of leukemia were not "found" by his study, thus "underestimating" the true excess risk (see Pet. App. 103a); he did not state that these workers were not in his cohort. Dr. Sakol also suggested that they were in Dr. Infante's cohort (Tr. 308-315). Moreover, even if it were necessary to increase the study population to include these cases, the risk would still increase dramatically—*i.e.*, instead of finding 7 leukemias in a population of 748, Dr. Infante might have found 16 out of 757. And, contrary to respondents' contention, the substantial likelihood that doctors may have misrepresented a worker's cause of death on his death certificate as aplastic anemia rather than leukemia, so that the worker's family would receive workmen's compensation, would lead to underestimation of the number of leukemia cases. The incentive to make that change exists only in connection with work-related deaths, not deaths in the general population.

leukemia * * * *ceased to occur*" (emphasis in original). This is not so. It is true that in the Aksoy study (Exh. 60), no new deaths were reported after a substitute was used in place of benzene by a studied cohort of shoemakers. However, the substitutes were analyzed at the time of the study by gas chromotography, and "[t]he result showed that the substitutes contained *no* benzene" (*id.* at 3) (emphasis added). Similarly, in the Vigliani study (Exh. 2-27) no new cases of leukemia were reported among certain workers in the rotogravure industry exposed to toluene after it was substituted for benzene in 1964 (Exh. 2-50 at 217). Although some forms of toluene contain trace amounts of benzene and other forms contain none (see Pet. App. 101a), Dr. Vigliani's study provides no basis for concluding that the substituted toluene contained benzene.[7]

[7] Respondents are correct that no excess cancer risk was found among workers at the same plants studied by Dr. Infante during a study by researchers from the University of North Carolina at a later time when benzene exposure had been reduced (but not eliminated) (Exh. 187 B-13). The researchers themselves, however, pointed out numerous flaws in their study that could have accounted for the lack of statistically significant leukemias (*id.* at 35). For example, for purposes of the study the plants were broken down into departments, and employees were classified in the department in which they had worked the longest. Some employees had changed jobs as many as 30 times. Therefore, employees were classified as belonging to a certain department, such as pliofilm, when in fact they may have spent 10% or less of their total work experience in that department (Exh. 187 B-13 at 25). In like fashion, an employee who worked in the pliofilm operation but spent a greater fraction of his total work experience elsewhere would not be classified under pliofilm operations. Moreover, the researchers noted that benzene was

The Secretary found each of the negative studies cited by respondents (API Br. 15) to be unreliable. The Stallones study of Shell Oil Company workers, for example, "could not determine how many [of the study group] were exposed to benzene" (Pet. App. 111a, 182a-183a). Likewise, the Tabershaw-Cooper study, among other failings, did "not delineate what proportion of the study population had ever been exposed to benzene" (*id.* at 108a); there was no "basis for identifying which workers may have been exposed to benzene" (*ibid.*); and fewer than 10% of the studied employees may have been exposed to benzene (Tr. 1358, 1363, 1411, 1438, 1977). The Thorpe study suffered from at least five substantial methodological faults (Pet. App. 110a, 182a-183a). Respondents are simply wrong in their assertion that the "uncontradicted evidence" proves the risk of cancer at low levels of exposure is "minuscule." The evidence considered as a whole supports both the Secretary's determination that no safe level of exposure to benzene is known and the Secretary's qualitative judgment that long-term exposure to benzene at 10 ppm poses an appreciable health risk.[8]

"suspect as a leukemogenic agent" and that exposure to benzene "should be maintained as far below the Threshold Limit Value as is possible" (*id.* at B. 5).

[8] The inability to quantify the excess risk hardly means that the risk is *de minimis*. For example, the studies (API Br. 4c & n.7) showing that asbestos is a "potent" carcinogen became available only after the Secretary had issued the standard for it. See 37 Fed. Reg. 11318 (1972) (asbestos dust).

c. Respondents' narrower theory also rests on the assertion that the Secretary did not "consider" evidence of costs and benefits and that the court below did no more than hold that the Secretary "must consider evidence on both benefits and costs" (API Br. 27 n.45). Once again, the record belies this assertion. As we explained in our opening brief, the Secretary did consider such evidence in detail. The Secretary simply concluded that the evidence was not sufficiently reliable to establish a safe level of exposure.

In connection with their narrower theory, respondents suggest (API Br. 27 n.45, 70) that it is unnecessary to consider in this case the substantive content of the second step in the court of appeals' test—the "reasonable relationship" requirement—inasmuch as the Secretary was unable to demonstrate quantifiable benefits. We disagree. The Fifth Circuit was moved to require a showing of quantifiable, if approximate, benefits in order to provide the type of "hard evidence" it felt was necessary to satisfy the cost-benefit test of *Aqua Slide 'N' Dive* v. *CPSC*, 569 F.2d 831, 837-844 (5th Cir. 1978). If no such test is required by the Occupational Safety and Health Act, then there is no justification for prohibiting the Secretary from relying on qualitative evidence of risk, especially where reliable quantification of the risk is not possible. We now turn to the arguments made by respondents in support of the actual holding below.

2. In support of the actual holding below, respondents argue that (i) the ultimate goal of the Act is to obtain the maximum possible health and safety benefits from the "finite industrial resources" available for health and safety protection, (ii) any "absolutist interpretation" of the Act will require standards so stringent that they will squander resources that might save more lives if used to combat future hazards, (iii) any such interpretation is thus inconsistent with the goal of the Act and is precluded by "pragmatic" concepts embedded in the statutory language and history, and (iv) the Secretary therefore "must set standards that are reasonable and practical, and in order to do so, must identify, at least roughly, the benefits that each standard is expected to achieve and to consider those benefits in light of the costs imposed by the standard" (API Br. 69-70). To satisfy this requirement the Secretary "must make" a "rough but educated" estimate of the excess risk using risk-assessment techniques (*id.* at 70). "Only if this is done," respondents conclude, can the Secretary carry his "affirmative burden" of "demonstrating" the "reasonableness" of the adopted standard (*ibid.*). If such quantification is not possible for a given substance, then the Secretary may not regulate at all, even when he makes a *qualitative* judgment, based on experience and scientific opinion, that substances pose occupational health hazards.[9]

[9] Respondents attempt to avoid stating directly that the Secretary may not substitute his qualitative judgment where

a. Respondents' contention that the Secretary's regulatory approach will severely misallocate the finite industrial resources available for occupational health protection is incorrect and rests on an extreme and unlikely hypothetical in which the Secretary would require an industry to exhaust its resources available for occupational health protection merely to eliminate a cancer risk known to be minimal. The Act provides ample protection against such extreme regulation and permits "pragmatic" consideration of costs, benefits, and risks in a number of ways.

First, 29 U.S.C. 655(g) requires the Secretary to establish priorities in setting occupational health and safety standards so that the more serious hazards are addressed first. In setting such priorities the Secretary must, of course, consider the relative costs, benefits and risks. Second, 29 U.S.C. 655(b)(5) comes into play after the Secretary decides to issue a new standard. Thus, if a rulemaking record affirmatively demonstrates that an existing standard is highly protective and that imposing a more stringent standard would threaten the industry's ability to respond to other health hazards without significantly improving health protection, the Secretary has dis-

quantitative evidence is too speculative by contending that reliable risk assessments may be performed for long-term, low-level exposure to benzene based on existing data. As explained above (see pages 2-11, *supra*), the Secretary found to the contrary. The Fifth Circuit, moreover, held that such quantitative assessments are a *sine qua non* of regulation under the Act (Pet. App. 18a-19a).

cretion not to issue the standard or to delay regulation until more immediate hazards are addressed. Third, even where the Secretary decides to issue a standard, he considers reliable epidemiological data to determine whether or not a safe level of exposure can be identified. Where such a safe level is determined, the Secretary sets the standard at *that* level, not at the lowest feasible level. Fourth, even where the Secretary requires the lowest feasible level to be achieved, the lowest level will often be dictated by technological feasibility well before the cost of the standard threatens the ability of the affected industry to respond to future hazards. In fact, no standard yet issued has disabled any industry from responding to future hazards.[10] In light of these procedures, the Secretary's view of the Act is hardly an "absolutist interpretation" and does not go nearly so far as the Endangered Species Act or other "absolute" statutes cited by respondents (API Br. 38, 66-68).[11]

[10] In addition, the Secretary may grant a variance from any standard to any employer whose methods of controls will provide at least as much safety and health as would the controls specified in the standard (see 29 U.S.C. 655(d)). The Secretary also takes economic feasibility into account in working out compliance programs for cited employers (see note 44 of our opening brief).

[11] Respondents' dichotomy between "absolute" statutes and "balancing" statutes is fallacious. OSHA is neither absolute nor a balancing statute like the Consumer Product Safety Act, but strikes its own balance in favor of maximum feasible health protection. This obvious difference makes it unnecessary to reply to respondents' treatment of other statutes, except as follows:

(i) The "safety" requirement of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301 *et seq.*, necessarily requires a balancing of the drug's health benefit against its health risk inasmuch as *all* drugs pose risks to patients. Monetary cost, however, is not a factor. Although *Hess & Clark, Division of Rhodia, Inc.* v. *FDA*, 496 F.2d 975, 993-994 (D.C. Cir. 1974), stated in dictum that the determination of whether an animal drug is safe involves weighing of costs and benefits, the Commissioner of Food and Drugs has specifically refused to follow the dictum. See Diethylstilbestrol; Withdrawal of Approval of New Animal Drug Application; Commissioner's Decision, 44 Fed. Reg. 54852, 54881-54883 (Sept. 21, 1979). Although the prohibition against substances "injurious to living man" in the pre-1972 language of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. (1970 ed.) 135(z)(2)(g) and (h), was construed to require balancing of the health benefits of continued use against health risks, such balancing was clearly suggested by the legislative history. *Environmental Defense Fund, Inc.* v. *Ruckelshaus*, 439 F. 2d 584, 594 n.36 (D.C. Cir. 1971); S. Rep. No. 1379, 89th Cong., 2d Sess. 13, 27, 52, 64-65 (1966).

(ii) Respondents argue (API Br. 67) that the provisions in the Federal Water Pollution Control Act Amendments of 1972, 33 U.S.C. 1311(b)(2)(A), directing that EPA's 1983 effluent limitation guideline reflect "the best available technology economically achievable * * * which will result in reasonable further progress toward * * * eliminating [pollution]," require a comparison of benefits to costs in the setting of limitations. In explaining the conference report on the FWPCA, however, Senator Muskie, "perhaps the Act's primary author" (*E.I. duPont de Nemours & Co.* v. *Train*, 430 U.S. 112, 129 (1977)), stated that in setting limitations for the "best available technology," EPA could consider cost but that "no balancing test will be required." 118 Cong. Rec. 33696 (1972). Even with respect to the 1977 limitations, which required only that limitations be achievable with the "best practicable technology," the statute provides for a limited balancing of costs and benefits: "The balancing test between total cost and effluent reduction benefits is intended to limit the application of technology only where the additional de-

Notwithstanding these features of the Act, respondents urge that once the Secretary decides to regulate a toxic substance whose elimination is technologically feasible (but only at great cost) his approach requires its complete elimination—even if that means fully depleting the affected industry's occupational health resources. Respondents would applaud this allocation were it the best use of the resources.[12] Respondents fear it will not be, however, because, as they construe the Secretary's position, he is barred altogether from considering the possibility that some or all of the resources might be better used to meet other health hazards.[13]

Respondents have falsely portrayed the Secretary's approach. The concept of the lowest feasible level has been developed in a far more realistic manner than respondents' extreme hypothetical would suggest. The costs of toxic substances standards have all been, as in this case, "well within the financial capability" of the affected industries (Pet. App. 163a). No standard has depleted any industry's occupational health resources. Moreover, just as here respondents have not identified any occupational health hazard within their industries more serious than benzene, it is unlikely that such evidence could ever be shown, for the Secretary has sought to address hazards in

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gree of effluent reduction is *wholly out of proportion* to the costs of achieving such marginal level of reduction * * *." *Ibid.* (emphasis added).

(iii) Respondents argue (API Br. 43-45 n.62) that the Federal Mine Safety and Health Act of 1977, 30 U.S.C. (Supp. I) 801 *et seq.*, is far more stringent than OSHA, but that even the Mine Safety Act "does not relieve the Secretary of his obligation to consider risk, benefit and cost evidence." A fortiori, they conclude that here the Secretary is not relieved of that obligation. But the Secretary did consider evidence of risk, benefit, and cost at length. Moreover, respondents neglect to mention that the legislative history of the Mine Act specifically approved and incorporated three leading OSHA cases holding that the Secretary must act under Section 655(b)(5) to protect employees even where "the ultimate facts ~~here~~ in dispute are 'on the frontiers of scientific knowledge,'" and that "standards may be economically feasible even though from the standpoint of employers, they are 'financially burdensome and affect profit margins adversely.'" 123 Cong. Rec. S10221 (daily ed. June 20, 1977); S. Rep. No. 95-181, 95th Cong., 1st Sess. 21-22 (1977), citing *Society of Plastics Industry, Inc.* v. *OSHA*, 509 F. 2d 1301 (2d Cir.), cert. denied, 421 U.S. 992 (1975); *AFL-CIO* v. *Brennan*, 530 F.2d 109 (3d Cir. 1975); *Industrial Union Department, AFL-CIO* v. *Hodgson*, 499 F.2d 467, 474 (D.C. Cir. 1974).

[12] Although respondents urge that all risks, benefits, and costs be "considered" in setting standards, they insist (API Br. 7 n.10) that the risk of nonmalignant blood diseases, some fatal, and chromosomal damage due to benzene exposure must be ignored in this case. Contrary to respondents' claim, the Secretary *did* rely on these nonmalignant health risks in deciding to issue the standard (Pet. App. 60a, 78a-98a, 132a, 180a-181a, 212a).

[13] Compliance with the benzene standard may itself substantially reduce the costs of compliance with future standards. Engineering controls like those required by the benzene standard have often proved successful in removing numerous airborne contaminants at the same time. For example, the engineering controls required by the coke oven emissions standard appear to ensure compliance by coke oven batteries with the benzene standard (Pet. App. 145a-146a, 175a, 177a, 191a). Similarly, compliance with the lead standard by primary lead smelters could significantly achieve compliance with the arsenic standard. See 43 Fed. Reg. 54354, 54494 (1978) (lead standard).

order of their severity (see 29 U.S.C. 655(g)). Hence, the Secretary's policy of setting the lowest feasible level is sound and advances the statutory objective.

Respondents would go further and require the assessment of relative cost and risk data for all present and future hazards throughout the industry, if not more broadly, in the establishing of permissible exposure limits for particular substances. But comprehensive risk assessments are not available for many hazards, much less for all hazards within an industry. Prediction of the relationship between an industry's future economic capability and the cost of future OSHA regulations to determine the proper allocation of present resources for the regulation of, say, benzene would be similarly fraught with uncertainty. See *BASF Wyandotte Corp.* v. *Costle*, 598 F.2d 637, 663 n.53 (1st Cir. 1979). In such circumstances, the government must act in the face of uncertainty and must weigh the danger that the health threat is even greater than perceived against the possibility that it is overstated. The advantage of waiting for more complete data must also be weighed against the immediate threat to health. The appropriate resolution of these competing factors is a policy judgment. In resolving such policy questions, the principle of risk aversion in the face of uncertainty—the natural inclination to play it safe, even at the risk of some economic inefficiency—is a well-established concept of public policy (see Pet. App. 97a).

Furthermore, the Secretary has never asserted that he is precluded from considering (where there

is some reason to believe it is so) whether the cost of a standard is sufficiently large that the affected industry will be unable to respond effectively to future health hazards. If that situation were to arise, the statutory phrase "most adequately assures, to the extent feasible" (Section 655(b)(5)) is sufficiently flexible to allow the Secretary to take into account in setting a standard the need for the industry to meet future threats to employee health. In short, there is no realistic basis for respondents' hyperbole that the Secretary's regulatory approach will lead to a severe misallocation of finite occupational health resources.[14]

b. In reply to respondents' contention that "pragmatic" features of the statutory language and history require the Secretary to identify quantifiable benefits and to demonstrate that they bear a reasonable relationship to the costs of the standard, we observe initially that respondents have all but abandoned (API Br. 67 n.96) reliance on the phrase "reasonably necessary or appropriate," the linchpin of the decision below. Our opening brief (at pages 42-47) stated the governing principle that where "the empowering provision of a statute states simply that the agency may 'make * * * such rules and regulations as may be necessary to carry out the provisions of [an] Act,' * * * the validity of a regulation promulgated thereunder will be sustained so long as

[14] "[T]o put an extreme case is not a good test of the fair and just interpretation of any statute." *United States* v. *Dickson*, 40 U.S. (15 Pet.) 141, 164 (1841) (Story, J.).

it is 'reasonably related to the purposes of the enabling legislation.'" *Mourning* v. *Family Publications Service, Inc.*, 411 U.S. 356, 369 (1973) (footnote omitted). Respondents' sole rejoinder (API Br. 67 n.96) is that none of the cases we cited involved statutes that contained the phrase "reasonably necessary or appropriate" and that that phrase, as used in the Consumer Product Safety Act, 15 U.S.C. 2051 *et seq.*, has been construed in two lower court decisions as the Fifth Circuit construed it below.[15]

[15] Congress has used the phrase "reasonably necessary or appropriate" in enabling clauses in several statutes. See, *e.g.*, Section 213 of the Public Utility Act of 1935, 16 U.S.C. 824c; Section 1 of the Veterans Mortgage Insurance Act, 38 U.S.C. 806(g)(4); Section 11(b) of the National School Lunch Act, 42 U.S.C. 1760(b); Section 1406(12) of the Housing and Urban Development Act of 1968, 15 U.S.C. 1705(12). In none of these does the legislative history or the context of the statutory language suggest that Congress meant to limit the agency's rulemaking power by the addition of the word "reasonable." See S. Rep. No. 621, 74th Cong., 1st Sess. 50 (1935) (Public Utility Act); S. Rep. No. 92-311, 92d Cong., 1st Sess. (1971) (Veterans Mortgage Insurance); S. Rep. No. 1123, 90th Cong., 2d Sess. 109 (1968) (Housing Act); H.R. Rep. No. 1585, 90th Cong., 2d Sess. (1962); 114 Cong. Rec. 23681 (1968) (same). To the contrary, in describing the enabling provision in the National School Lunch Act containing the phrase "reasonably necessary or appropriate" (H.R. Rep. No. 684, 79th Cong., 1st Sess. 6 (1945)), the House Report stated that it directed the Secretary of Agriculture to impose certain requirements "as in his opinion are necessary to effectuate the purposes of this title," thus describing the phrase "reasonably necessary or appropriate" in precisely the same way that the Court has traditionally construed enabling clauses (see our opening brief at 42-48.)

Although the Court has never construed the precise phrase "reasonably necessary or appropriate," that phrase could hardly be more rigorous than simply the word "necessary." Indeed, the word "reasonable" in a statutory provision authorizing promulgation of "reasonable regulations" implies no balancing test but merely requires that the regulations be "rational" in light of the purpose of the statute. *United States* v. *Allegheny-Ludlum Steel Corp.*, 406 U.S. 742, 752-753 (1972). And, although other provisions in the Consumer Product Safety Act expressly require certain balancing of costs and benefits of safety rules, the phrase "reasonably necessary and appropriate" does not. Hence, to the extent that the decisions relied on that phrase for their results, they were in error. See *Aqua Slide 'N' Dive Corp.* v. *CPSC*, 569 F.2d 831, 844 (5th Cir. 1978); *D. D. Bean & Sons* v. *CPSC*, 574 F.2d 643 (1st Cir. 1978).[16]

c. Respondents' contention (API Br. 41-47, 8b-9b) that the word "feasible" was inserted into 29 U.S.C. 655(b)(5) for the specific purpose of requiring that standards be "reasonable" and "practical," even if true, does not support the holding below. There is nothing unreasonable about a legislative determination that requires standards to be set as low as technologically and economically feasible in order to

[16] Significantly, the phrase was part of the OSHA bill from its inception. At no time in the vigorous debates over the cost of complying with the Secretary's health standards was there ever a suggestion that the phrase was a brake on the Secretary's rulemaking power (see our opening brief at 43 n.36). Respondents do not reply to this argument.

assure that the calculus is weighted in favor of occupational health. Cf. *Usery* v. *Turner Elkhorn Mining Co.*, 428 U.S. 1, 28-29 (1976). A standard, moreover, may be "reasonable" and "practical" even if its benefits are not measurable. Indeed, it is unreasonable and impractical to deny health protection urged by the public health community merely because the number of lives at stake is not susceptible to reliable measurement. Respondents' strained effort to import the words "reasonable" and "practical" into the word "feasible" is therefore beside the point.[17]

[17] In any event, respondents' effort is unpersuasive. In essence, they argue (API Br. 8b-10b) that Senator Javits, the author of the feasibility amendment, intended the word "feasible" to comprehend "reasonable" and "practical." The thread of the argument begins with the Nixon Administration's original bill (S. 2788, 91st Cong., 1st Sess. (1969)), introduced by Senator Javits, which would have required the board responsible for issuing health and safety standards to submit its proposals to certain organizations for a report on "the technical feasibility, reasonableness and practicality of such standard." *Subcomm. on Labor of the Senate Comm. on Labor and Public Welfare*, 92d Cong., 1st Sess. *Legislative History of the Occupational Safety and Health Act of 1970* (Comm. Print 1971) (hereinafter "Leg. Hist.") 38-39. 115 Cong. Rec. 22511 (1969). Respondents claim (API Br. 42) that Senator Javits "described" the provision in the bill calling for a report on "technical feasibility, reasonableness, and practicality" as a "report on the feasibility of the proposed standards," thus collapsing all three words into "feasible."

In fact, however, Senator Javits did not "describe" the report in such terms at all. The "description" of the report was made in President Nixon's message concerning the Administration bill, not by Senator Javits. 115 Cong. Rec. 22511, 22517 (1969). Senator Javits merely asked that the President's lengthy message be printed in the Congressional Record (115 Cong. Rec. 22511 (1969)). Rather than endorsing the message, Senator Javits disassociated himself from the

Administration's bill on a variety of issues, saying that "it may be desirable to go somewhat further than this bill does in strengthening the hand of the Federal Goverment in this area" (*id.* at 22512). Significantly, when Senator Javits actually described his feasibility amendment he consistently used only the word "feasible" and never equated it with "reasonable" or "practical" (Leg. Hist. 197, 418). Furthermore, the President's summary itself did not equate the words "reasonable" or "practical" with "feasible" or even use the words "reasonable" or "practical." The summary stated only that the organizations' reports would address "feasibility" without stating whether it would address other matters. 115 Cong. Rec. 22517 (1969).

The related contention (API Br. 8b) that Senator Javits' feasibility amendment "succeeded in reconciling the Williams bill with the Administration view on this issue [of collapsing the three words into feasible]" ignores the fact that Senator Javits stated that the Senate Committee bill was "an improvement over * * * the administration bill, which contains no criteria for standards at all." (Neither the original Administration bill nor the Steiger-Sikes bill contained any criteria for standards. The Steiger-Sikes bill, moreover, contained no requirement for a report on feasibility, reasonableness or practicality. See Leg. Hist. 36-42, 770-776.) Hence, rather than believing he had incorporated "reasonableness" and "practicality" criteria for standards from the Administration bill or the Steiger-Sikes bill, Senator Javits believed these latter bills had no criteria at all for standards.

Respondents do not seriously dispute that every court of appeals (other than the Fifth Circuit in this case) that has considered the role of costs in promulgating toxic-substance standards has upheld the Secretary's interpretation of the feasibility requirement. Respondents resort to cases construing the word feasible in the OSHA noise standard. *Turner Co., Div. of Olin Corp.* v. *Secretary of Labor and OSHRC*, 561 F.2d 82 (7th Cir. 1977); *RMI Co.* v. *Secretary of Labor and OSHRC*, 594 F.2d 566 (6th Cir. 1979). The noise standard, 29 C.F.R. 1910.95(b)(1), requires employers to utilize "feasible administrative or engineering controls" to reduce employee exposure to excessive noise. It also requires the use of personal protective equipment if administrative or engineering controls are either infeasible or do not reduce

d. Contrary to respondents' argument (API Br. 44-47), the substitution of the word "material" for "any" in 29 U.S.C. 655(b)(5) was not meant to prohibit standards except where there is a measurable, material probability of injury posed by the hazard. To the contrary, "material" modifies "impairment," not the probability that it will occur:

> The Secretary * * * shall set the standard which most adequately assures, to the extent feasible, * * * that no employee will *suffer material impairment of health or functional capacity* * * *

An "impairment of health or functional capacity" is not a "risk." It is a condition or disease, such as illness due to leukemia. An employee, moreover, does not "suffer" a risk. He "suffers" a disease or in-

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exposure to within prescribed limits. *Turner* (which was relied on in *RMI*) reasoned that the noise standard was initially promulgated pursuant to the Walsh-Healey Act, which contained no requirement that standards be feasible, and was adopted as a national consensus standard pursuant to Section 655(a) of OSHA without further consideration of feasibility. 561 F.2d at 85. It reasoned that fairness therefore required that economic feasibility be relevant to enforcing the standard. *Ibid.* We disagree. At most, this calls for interpreting "feasibility" to include consideration of cost—not to require a balancing of costs and benefits. Moreover, the court premised its balancing requirement on the fact that excessive noise is only one of many hazards, many of which are life threatening, which the Act seeks to eliminate; consequently, an employer ought not be required to allocate too much of his finite resources on this lesser hazard. *Id.* at 86; see *Continental Can Co.*, [1976-77] O.S.H.D. (CCH) ¶ 21,009 at 25,256 (1976). As we have discussed, however, the assignment of priorities to hazards is a legislative judgment assigned by the Act to the Secretary.

jury, *i.e.*, an impairment. There is thus no warrant for reading this sentence as if it read: "* * * no employee will suffer [*i.e.*, experience] material *risk of* impairment of health or functional capacity * * *." To do so, moreover, would reduce the command of Section 655(b)(5) to a nullity, for the probability of contracting cancer from exposure to industrial carcinogens, although in excess of normal risks, is small by comparison to other possible causes of death and thus not itself "material." [18]

The Secretary's interpretation of "material" is supported by the judicial construction of the comparable language in 29 U.S.C. 666(j), which sets forth the criteria for determining whether a violation of the Act will be deemed "serious" in the enforcement context. A violation will be deemed serious if, *inter alia*, "there is a substantial probability that death or serious physical harm could result" from the cited hazard. The courts have consistently held that a violation is deemed serious under the Act "where, although the accident itself is merely possible (*i.e.*, in statutory terms, 'could result from a condition'), there is a substantial probability of serious injury *if it does occur*." *Shaw Const., Inc.* v.

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[18] What little legislative history exists on the insertion of the word "material" supports our view that it was addressed to the type of injury, not the probability of injury. Senator Saxbe, one of Senator Dominick's allies in this matter, complained that the phrase "any impairment" would cover mosquito and black-fly bites (Leg. Hist. 345). Senator Williams, a primary sponsor of the legislation, fully supported the amendment and felt that the change "strengthens the objec-

OSHRC, 534 F.2d 1183, 1185, n.4 (5th Cir. 1976) (emphasis added). See *Usery* v. *Hermitage Concrete Pipe Co.*, 584 F.2d 127 (6th Cir. 1978).

e. Contrary to respondents' argument (API Br. 51-55), the second and third sentences of 29 U.S.C. 655(b)(5), and the best-available-evidence clause of the first sentence of Section 655(b)(5) do not support the holding below. Those provisions impose *procedural* requirements to ensure that certain factors are considered. Their substantive weight in setting OSHA standards is dictated by the first sentence of Section 655(b)(5).[19]

Moreover, these procedural imperatives do not prohibit the Secretary from issuing a standard where the number of lives at issue cannot be reliably predicted. The Court has long held that where the

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tives of standards that will protect against physical impairment and loss of function" (Leg. Hist. 503). It is inconceivable that a radical change prohibiting regulation of carcinogens except where a measurably material probability of death would be averted was intended by this virtually unnoted shift in language. See *Edmonds* v. *Compagnie Generale Transantlantique*, No. 78-479 (June 27, 1979), slip op. 9-10.

[19] A statutory requirement that certain factors be "considered" in rulemaking does not require the agencies to give the factors any particular substantive weight or permit a reviewing court to substitute its judgment concerning the weight to be given mandatory considerations. See, *e.g.*, *Kleppe* v. *Sierra Club*, 427 U.S. 390, 410 n.21 (1976); *Aberdeen & Rockfish R.R.* v. *SCRAP*, 422 U.S. 289, 319 (1975); *Vermont Yankee Nuclear Power Corp.* v. *NRDC*, 435 U.S. 519, 558 (1978); *New York* v. *United States*, 331 U.S. 284, 347-349 (1947).

"benefits" of regulation "do not lend themselves to detailed forecast," agencies have traditionally been "entitled to rely" on their "judgment, based on experience" and "deductions based on the expert knowledge of the agency." *FCC* v. *National Citizens Committee for Broadcasting*, 436 U.S. 775, 797, 814 (1978). "[S]pecific findings of tangible benefit" are not required. *FCC* v. *RCA Communications, Inc.*, 346 U.S. 86, 96 (1953). The agency may rely on its "informed discretion." *Panama Canal Co.* v. *Grace Line, Inc.*, 356 U.S. 309, 317 (1958). Accord, *Permian Basin Area Rate Cases*, 390 U.S. 747, 811 (1968); *Ethyl Corp.* v. *EPA*, 541 F.2d 1, 26-27 (D.C. Cir.), cert. denied, 426 U.S. 941 (1976). These principles apply all the more where "the questions involved in the promulgation of [OSHA] standards are on the frontiers of scientific knowledge, and consequently as to them insufficient data is presently available to make a fully informed factual determination" and rulemaking "must * * * depend to a greater extent upon policy judgments and less upon purely factual analysis." *Industrial Union Department, AFL-CIO* v. *Hodgson*, 499 F.2d 467, 474-475 (D.C. Cir. 1974).[20]

Nothing in the provisions cited by respondents alters this established rule. The first and second sentences of Section 655(b)(5) require only that the standard be based on the "best available evidence"

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[20] This passage from *Industrial Union Department* was cited with approval by the Court in *FCC* v. *National Citizens Committee*, *supra*, 436 U.S. at 814.

and on "research, demonstrations, experiments, and such other information as may be appropriate." The benzene standard *is* based on extensive research, demonstrations and experiments, as the voluminous record on file makes clear. The best available evidence was considered and the standard was based on it. The Senate Report, moreover, emphasizes that the Secretary retains discretion in deciding how much and what type of evidence is "appropriate." Leg. Hist. 147. Here, the Secretary concluded that it was not "appropriate" to postpone the standard until, if ever, better dose-response data permits a prediction of "measurable benefits." The third sentence of Section 655(b)(5) merely requires the Secretary to "consider" the "latest available scientific data in the field," the "feasibility" of the standard, "experience gained under this and other health and safety laws" and "attainment of the highest degree of health and safety protection for the employee." Again, however, the Secretary "considered" all these items in great detail. In the absence of a clear statutory directive that incremental risk assessments (and cost-benefit studies) *must* be made in every case, no matter how speculative they may be, these provisions should not be construed to rob the Secretary of his discretion to rely on his qualitative judgment, based on experience and informed by the best available evidence, rather than on extrapolations that the Secretary finds are too speculative to be of meaningful assistance in setting OSHA standards.

Nor does the substantial-evidence test preclude reliance on views, arguments or sound reasoning in evaluating rulemaking evidence. Congress required judicial review on the basis of substantial evidence because of concern that the Secretary of Labor might issue standards without a hearing, an official record, or the opportunity for judicial review. See Leg. Hist. 298-299, 1053. To check this possibility, Congress required factual determinations to be based on substantial evidence in the record, and authorized pre-enforcement review. At no time, however, did the sponsors of the substantial-evidence test state that the Secretary could not employ sound reasoning and judgment to assess the *significance* of the evidence in the record and to decide what, if any, standard might serve the purposes of the Act.[21] This is pre-

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[21] Indeed, the very materials relied on by respondents acknowledge the contrary. Even the six minority members of the House Committee so often cited by respondents felt that the standards should be based on "sound reasons." Leg. Hist. 884. Both the original Nixon Administration bill and the Steiger-Sikes substitute bill would have allowed rulemaking based on "views and arguments" as well as other "evidence" (Leg. Hist. 85, 771-772). Respondents themselves (API Br. 70-74) concede, as the courts of appeals have uniformly held (see our opening brief at 44-45 n.37), that the statutory test only requires the Secretary's factual determinations to be based on substantial evidence and does not subject the policy considerations relied on by the Secretary to any standard of review other than the determination whether they are consistent with the purpose of the Act.

[Footnote continued on page 30]

[21] [Continued]

Respondents' lengthy and distorted rendition of the legislative history on this point deserves a somewhat extended reply:

(i) Respondents claim (API Br. 3b, 6b) that opponents of the Daniels and Williams bills assailed " 'unfair regulatory procedures' which 'permit adoption of administrative regulations based on "views and arguments" rather than solely on probative evidence.' " With one exception, however, the citations to the legislative history have nothing to do with this point and concern exclusively the failure of the bill to use an independent board to set standards (Leg. Hist. 474-475, 877, 982, 1014). The one citation that does bear on this point (*id.* at 884), as mentioned, shows that even the opponents of the statute felt the standard setter should consider "sound reasons."

(ii) Respondents claim (API Br. 53-54 & n.75, 126) that Senator Cook remarked that on judicial review of standards employers would "[n]ever win a case" under the arbitrary-and-capricious test. Actually, Senator Cook's statement had nothing to do with judicial review of health standards. His criticism was confined to a provision in the Senate bill that allowed the Secretary to veto state health and safety plans without adequate judicial review (Leg. Hist. 342-344).

(iii) Respondents compound this error by claiming (API Br. 54, 18b & n.19) that Senator Cook's objection was "one of the chief concerns" that led the full House to reject the Committee bill and to substitute, among other things, the substantial-evidence test. The citations that follow this claim (Leg. Hist. 1013, 1014, 1016, 1053, 1062) do not mention either the arbitrary-and-capricious or the substantial-evidence test. All are concerned with the question whether standards should be set by an independent board (Leg. Hist. 1013, 1014, 1016, 1053, 1062). Only one citation (*id.* at 1053) is relevant to respondents' assertions, but it contradicts their point. Representative Sikes objected to the House Committee bill because it contained "no provision for judicial review of standards." Representative Sikes, however, made quite clear that he would have accepted "the Senate-passed" bill, which *did* "provide such review" (*ibid.*). Since the Senate-passed bill provided for judicial review only under the arbitrary-and-

cisely the function of an expert administrator or agency.

f. Contrary to respondents' suggestion (API Br. 55-64, 11c-14c), the Court should defer to the statutory construction of the Secretary, not the Occupational Health and Safety Commission. The Secretary, not the Commission, is the official entrusted by Congress with the responsibility to study occupational health and safety hazards and to set standards for them. The Commission has no experience or responsibility in investigating or regulating such hazards. The Act does not authorize the Commission to review the validity or wisdom of standards. It may only

capricious standard (see Leg. Hist. 245-246), it is clear that Representative Sikes was objecting solely to the total absence from the House Committee bill of any express provision for pre-enforcement review (*id.* at 940-945).

(iv) Respondents further claim without citation (API Br. 10b) that the second and third sentences of 29 U.S.C. 655(b)(5) were added to prevent the Secretary from acting "on the basis of 'views' or 'arguments.' " However, neither the Senate majority nor minority reports nor any individual Senator ever made such a statement (Leg. Hist. 141-203), and it is totally unsupported. It is true, as respondents relate (API Br. 12b), that the Senate bill was criticized by administration supporters for not requiring a "record" and the substantial-evidence test (Leg. Hist. 298-299). Significantly, however, this was merely a criticism of the informal rulemaking procedure (under 5 U.S.C. 553) allowed by the Senate bill. It was not a criticism of the use of views, arguments or reasoning in the rulemaking process. To the contrary, as mentioned, the Nixon Administration bill and the Steiger-Sikes substitute bill provided for "on the record" rulemaking under the APA, followed by judicial review (Leg. Hist. 110-111).

adjudicate alleged violations of standards drawn by the Secretary. Compare 29 U.S.C. 655(f) with 29 U.S.C. 659. The Commission thus has no occasion to pronounce authoritative constructions of Section 655(b)(5). Its construction of words and phrases in the standards themselves in enforcement cases cannot control the meaning of the rulemaking provisions of the Act. In these circumstances, and in light of the congressional intention not to delegate standard-setting power to an independent commission (see Leg. Hist. 148, 462, 1186-1187, 1191, 1192, 1201-1202), the Secretary's, not the Commission's, view of 29 U.S.C. 655(b)(5) warrants deference.[22]

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[22] Respondents are wrong in their assertion (API Br. 57) that the Secretary and the Assistant Secretary for OSHA have contradicted their position in this case. Although risk assessments were performed in connection with the lead and cotton dust standards, the data were used only to identify health benefits, not to set the level of protection by balancing costs and benefits. See 43 Fed. Reg. 54354, 54427-54431 (1978) (lead); 43 Fed. Reg. 27350, 27378-27379 (1978) (cotton dust); see our opening brief at 68 n.55. The cost-benefit analysis of the cotton dust standard cited by respondents was performed at the expressed request of Congress *after* the standard's promulgation. The report to Congress cautions that "this is a new analysis and does not reflect the decisionmaking process used to promulgate the final standard." U.S. Dept. of Labor, Report to Congress—Cotton Dust: Review of Alternative Technical Standards and Control Technologies 6-7 (May 14, 1979). Similarly, although the preamble to the lead standard stated that the regulation could satisfy the Fifth Circuit's balancing test if one were required, it emphasized that the Secretary "does not accede to the Court's interpretation of the Act." 43 Fed. Reg. 54431 (1978).

The speech by Secretary Marshall simply stated that costs and benefits were "acknowledged"; he did not state that

3. Implicit throughout respondent Rubber Manufacturers Association, Inc.'s submission (RMA Br. 5, 8, 13 n.23) is the suggestion that the dermal prohibi-

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the two factors were balanced in establishing permissible exposure levels for toxic substances. See U.S. Dept. of Labor, Office of Information News Release, Speech Prepared for Delivery by Secretary of Labor Ray Marshall Before the League of Women Voters, Oakland, California at 8 (March 24, 1979). And, after Dr. Bingham's testimony before the Senate Appropriations Committee cited by respondents (API Br. 13c), she sent a letter to the committee chairman to clarify OSHA's position, stating that the agency sets standards by a two-step process, first "determin[ing] * * * the level of protection needed to most adequately assure workers' health," then assessing "the technological and economic capabilities of affected industries" to determine if the standard is "feasible." Appendix B, *infra*, 15a. She explained that the agency "do[es] not believe that a rigid cost-benefit formula should be utilized in the standard setting process. Moreover, incremental cost-benefit analysis is far too theoretical to be applicable, given the limitations of existing methodologies and data bases." *Id.* at 17a.

Nor did the Secretary balance costs and benefits in his 1974 standard regulating 14 carcinogens, as API suggests (API Br. 13c & n.35). Respondents correctly point out that the Secretary set a lower percentage exclusion for "substances [that] are known to be potent human carcinogens." However, the stated intent of all the exclusions was to "avoid substantial obstruction, if not stoppage, of the use of many processes and products which are considered useful in industry and even in cancer research, and about which the record contains very little information" (39 Fed. Reg. 3756, 3759 (1974)), *i.e.* to set a feasible level. Although the Secretary's explanation of his rationale is admittedly ambiguous, that ambiguity was eliminated as the Secretary's regulation of carcinogens evolved, as illustrated by subsequent standards (see pages 67-69 n.55 & 73 n.59 of our opening brief). In any event, the 14-carcinogens standard clearly did not adopt a policy of cost-benefit balancing in the regulation of health hazards.

tion and protective clothing requirements are not feasible. The standard, however, is intended to prohibit dermal and eye contact only with liquids containing more benzene than can feasibly be eliminated. The prohibitions do not apply at all where the liquids contain less than 0.5% benzene (0.1% after three years). Even at the time of the amendment proceeding, at least one supplier sold and several users already used solvents containing less than 0.1% benzene (A. 190, 199, 249). The Secretary found that the three-year phase-in would allow adequate time for suppliers to achieve the 0.1% level (A. 266). In any event, since the feasibility issue was not reached below, it must be assumed in these proceedings that the challenged provisions, together with the percentage exclusion, are entirely feasible.

The issue now presented is whether, having found that the Secretary's conclusion that dermal and eye contact poses a health risk is supported by substantial evidence,[23] the Fifth Circuit correctly held that the Act requires the Secretary to delay the challenged pro-

[23] The substantial evidence supporting this determination is summarized at pages 27-28 of our opening brief. The substantial evidence test, of course, does not require conclusive evidence. *FPC* v. *Florida Power & Light Co.*, 404 U.S. 453, 467-468 (1972). RMA erroneously argues (RMA Br. 14 n.25) that the court below did not hold that substantial evidence supported the finding that dermal and eye contact poses a health risk. To the contrary, the court held that even though substantial evidence supported that finding, the Secretary "in light of OSHA's statutory command" (in the second and third sentences of Section 655(b)(5)), was required to compile a "complete" record by acquiring the Maibach-type study (Pet. App. 25a-27a).

visions until additional and unavailable evidence is acquired. The Secretary can hardly be expected to hire contractors (or request NIOSH) to perform new studies each time it is suggested that such studies might shed new, even significant, light on the best evidence available at the time. Any such requirement would hopelessly bog down the agency in a mire of suggestions for additional research, and no standard would ever issue. Necessarily, the Secretary enjoys discretion to determine when it is "appropriate" to delay promulgation of a standard in order to acquire new evidence. See 29 U.S.C. 655(b)(5) (second sentence) and Leg. Hist. 147, 848. An exercise of such discretion can be reviewed only for the "clearest abuse of discretion" (see our opening brief at 82 n. 67).

Assuming that there ever could be an abuse of discretion in declining to procure additional studies where the Secretary considers the best available evidence and reaches a conclusion based on substantial evidence, there was no abuse of discretion here in the Secretary's decision not to delay the dermal-eye and clothing provisions until a Maibach-type study was performed. As the Secretary explained (Pet. App. 192a-194a, 211a-213a), (i) industry generally did not oppose the provisions now challenged (so long as a feasible percentage exclusion was adopted), (ii) many employers already recognized the health risk and required protective clothing, (iii) NIOSH, ACGIH and other standard-setting organizations recommended elimination of skin contact with liquids containing benzene, (iv) certain studies and experts have concluded that benzene is

"readily adsorbed" into intact skin, although at an unknown rate, (v) "considerable amounts" can be absorbed through damaged skin, and (vi) repeated skin contact with benzene causes skin irritations and dermatitis (see Pet. App. 80a, 212a). In these circumstances, the Secretary did not abuse his discretion in declining to delay the standard (or its challenged provisions)[24] until it could contract with private consultants or induce NIOSH to perform a Maibach-type study, which itself might well have proved inconclusive (as it ultimately did; see pages 79-80 n.63 of our opening brief).[25]

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[24] Contrary to RMA's assertion (RMA Br. 10 n.17, 40-41), the agency's proposed policy for carcinogen regulation, which permits delays in the *initiation* of proceedings to classify a toxic substance as a carcinogen where new scientific evidence will soon be available, does not require the agency to stay a standard *already promulgated*. Nor does it require the agency to develop the new evidence. The policy simply permits postponements in the initiation of a classification proceeding to allow industry and others to submit new evidence in progress. Nonetheless, even after promulgation of a standard, the agency will consider new evidence suggesting need for a modification of the standard (see 29 U.S.C. 655(b)(1)).

[25] Moreover, Dr. Maibach's most recent scientific submission to the Court confirms the Secretary's conclusion that benzene is indeed absorbed through contact with human skin. Significantly, the study also finds that absorption through the palm—the part of the body in direct contact with solvents in tire-building (A. 191)—is substantially greater than in the forearm, at least in the rhesus monkeys used by Dr. Maibach in his test. As a result, RMA (and Drs. Maibach and Johnson) shift ground and argue, utilizing quite a number of questionable assumptions, that the amount of benzene absorbed through a worker's skin is far less than the benzene absorbed through his lungs and therefore that skin absorption need not be protected against. The short answer to this suggestion is that the Secretary must eliminate hazards to the extent feasible. It may not be feasible to achieve airborne concentrations less than one ppm. It is feasible to prohibit dermal and eye absorption.

CONCLUSION

The judgment of the court of appeals should be remanded with instructions to dismiss the petitions for review.

Respectfully submitted.

WADE H. MCCREE, JR.
Solicitor General

OCTOBER 1979

APPENDIX A

RISK ASSESSMENT UNCERTAINTY

The limitations of estimating the number of lives at risk due to long-term, low-level exposure to benzene are illustrated by the Wilson and the EPA studies (A. 15-29, 77-94, 158-179). Although the two calculations were based on the same mathematical method of extrapolation, they employed a number of different assumptions and yielded markedly different results.

The procedure for extrapolating risks was presented in mathematical form in the EPA's report (A. 18-28) and in graphical form in Wilson's report (A. 170). The general principle is that the adverse health effects observed in one or more groups of workers exposed to benzene at various levels can be used to predict the risk to other workers exposed to benzene (now and in the future) at much lower levels. To do so requires explicit assumptions about the relationships between leukemia incidence, intensity of exposure, duration of exposure, and other relevant factors such as age, latent period, etc.

The application of this principle is illustrated by Dr. Wilson's graphical plot of the relationship between the reported incidence of leukemia in workers and the concentrations of benzene to which they were exposed. The result of four epidemiologic studies (by Vigliani, Infante, Thorpe, and Aksoy) were marked on this plot in the form of crosses, the vertical and horizontal lines representing Dr. Wilson's estimates of the uncertainties in each set of data. (Dotted

arrows attached to the Infante and Vigliani data reflect Dr. Wilson's opinion that the exposure levels may have been systematically underestimated in these studies, in addition to the reported range of uncertainty or variation.) Dr. Wilson's estimate of the dose-response relationship for benzene-induced leukemia in man rejects the Infante study and is represented by the *lowest* of the three straight lines drawn on his graph (A. 170-171). This line was then used to estimate the lifetime risk of leukemia in hypothetical workers exposed to benzene at a concentration of 1 ppm (A. 170). Exactly the same procedure was used in the EPA report although it estimated a much higher slope for the dose-response relationship and used it to estimate risks to the general population rather than to workers.

As we show below, each calculation incorporated, explicitly or implicitly, a number of other assumptions, each of which introduces a further wide range of uncertainty into the final estimates of risk. Some of these uncertainties result from lack of scientific understanding of the mechanisms of carcinogenesis, whereas others result from specific deficiencies or gaps in the data on the effects of exposure to benzene. Although EPA pointed out the wide range of uncertainty in their estimates, Dr. Wilson did not do so, leaving an entirely spurious impression of precision.

1. *Selection of data from which to extrapolate* (see Pet. App. 81a, 120a, 122a, 125a). The first step in each calculation was to review the available epidemiologic data and to select one or more sets

of data as a "reference set" from which to extrapolate. Although the various epidemiologic studies on benzene were discussed extensively in the record, neither EPA nor Dr. Wilson reviewed them in detail or gave more than a cursory explanation of their selection. EPA based its estimates upon the results of the Infante study (A. 17-24). On the other hand, Dr. Wilson believed "that the Infante data cannot yet be taken literally" (A. 171) and he drew a much lower line on his graph (A. 170). Dr. Wilson's graph illustrates the great importance of this initial selection of data: the studies of Infante, Vigliani and Aksoy all arrive at different results and a dose-response curve drawn through any one of them would be different from that drawn through the others. In fact, Dr. Wilson's own estimate of the dose-response relationship is incongruent with any of the data. The range of uncertainty due to the initial selections of data is illustrated by comparing the extremes: the Infante study reported a 400% excess risk [1] in workers exposed, according to the Industrial Commission of Ohio, to 10-15 ppm (Pet. App. 105a), whereas the Aksoy study reported a 100% excess risk in workers exposed to about 200 ppm (Pet. App. 101a). Thus, even assuming the reliability of these data and assuming that the studies are comparable in other ways, estimates of the incre-

[1] Dr. Infante reported an incidence five times larger than that in the control populations, which have an incidence of one. The portion of the increased incidence attributable to benzene exposure thus is four times that in the control populations.

mental risk per unit of exposure may vary within a range of 1 to 80 (100/200 to 400/10).

2. *Uncertainties in data on leukemia incidence in the reference populations* (see Pet. App. 81a, 99a, 102a-103a, 107a, 109a, 112a, 122a, 124a). Once a study is selected as the basis for extrapolation, substantial uncertainties may arise from deficiencies in the data on leukemia incidence. These deficiencies, which were extensively discussed in the record, include incomplete follow-up of the exposed workers and both advertent and inadvertent errors in recording causes of death. In addition, there are several different types of leukemia, and benzene may pose different risks for each. For example, in the Infante study the relative risk was five-fold when all types of leukemia were considered, but ten-fold when only myeloid and monocytic leukemia were considered (Pet. App. 107a). Also, in this study only 75% of the exposed cohort were traced, so that the actual incidence of leukemia may have been substantially higher than that recorded (*Id.* at 104a).[2] It is difficult to estimate the possible range of uncertainties resulting from these factors, but it appears likely that the reported frequency of the relevant types of leukemia could easily be underestimated by a factor of two or more.

3. *Uncertainties in the level of exposure of the reference populations* (see Pet. App. 96a, 104a,

[2] Indeed, there was evidence in the record that additional cases of leukemia occurred in the exposed population. See our opening brief at 16 n.17. Dr. Infante assumed that the 25% unaccounted for were still alive, thus underestimating the excess risk (Pet. App. 104a).

105a). Large uncertainties in the range of concentrations of benzene to which the study populations were exposed were discussed in the preamble (Pet. App. 104a). The uncertainties arise not only from the paucity of actual measurements of benzene levels in the various workplaces, but also from the likelihood that the levels would have fluctuated and that the workers' exposure to benzene would have varied due to the use of respirators. Certain evidence showed benzene concentrations in one of the two plants studied by Dr. Infante as having been generally between zero and 10-15 ppm (Pet. App. 105a). EPA, however, estimated that benzene concentrations were generally in the range of 15-100 ppm and calculated that the average exposure might have been in the range 23.7-40 ppm (A. 24-25). Respondents claim that average concentrations were as high as 100 ppm (API Br. 12-13); and Dr. Wilson marked this possibility with a query on his graph (A. 170).[3] Even if the air in work places was this high, personal employee exposure may well have been quite low due to company requirements that employees wear respira-

[3] In this connection, respondents erroneously state (API Br. 13) that, one of "[t]he authors of the Infante Study * * * testified that OSHA had gone 'off the deep end' in interpreting the Study as demonstrating that 'exposure generally below 25 ppm have already induced leukemia." The witness and other authors of the study actually testified that it was impossible to reconstruct accurately the actual exposure levels and that the levels could have been below 10 ppm (Tr. 815, 928, 992, 996, 1141).

tors (see Tr. 807, 966, 972-973, 992, 996). Thus, for the Infante study there is at least a 10-fold range of uncertainty between the highest and lowest estimates of benzene concentrations, without considering any uncertainties resulting from variations within the workplace. (A "conservative" resolution of these uncertainties would require that the steepest possible line be drawn through the Infante "zone" on Wilson's graph. This would result in a slope of about 60 times that used by Dr. Wilson, or a risk of 10^{-4} per year per ppm if all Wilson's other assumptions are followed.)

4. *Uncertainties in the duration of exposure of the reference population* (see Pet. App. 104a; Tr. 767, 934). Carcinogenic risks are dependent on the duration of exposure. OSHA standards must protect workers exposed throughout their working lives. Hence, if observational data are to be used to predict risks to such workers, they should be derived from studies of workers exposed for most or all of their working lives. If they are based on studies of workers exposed for short periods, the calculated risks will be underestimated by unknown factors.

Dr. Wilson made no explicit assumption about the duration of exposure of his reference populations. EPA assumed that all workers in the Infante study were exposed continuously from their entry into the factory until 1975, *i.e.*, for 25-35 years (A. 25). However, there is no support for this assumption in the original report, which merely stated that "all

white males having had direct exposure to benzene *at any time* during the period of January 1, 1940 through December 31, 1949 were selected for study" (Exhibit 2A-271, p. 5, emphasis added). In the absence of information on job turnover among the workers who were studied, there is no reason to assume that the average duration of exposure was 30 years, rather than 15 years, 5 years, or even one year.[4] Thus the lack of information on this factor gives rise to at least a 10-fold range of uncertainty in the calculated risk per unit of exposure.

5. *Uncertainties in the extension of partial-lifetime mortality data to predict full-lifetime risks.* The observational data in the epidemiologic studies usually refer to the mortality experience of workers followed for only *part* of their lifetimes. To estimate the full magnitude of the risks, it is necessary to make assumptions about the excess mortality in the reference groups during the remainder of the workers' lives. Both EPA (A. 24-25) and Dr. Wilson implicitly assumed for the purposes of calculation that the risks observed in the younger years would not increase as the workers aged, so that their lifetime risks of contracting leukemia could be estimated by multiplying the relative risks observed in the studies by the lifetime incidence of leukemia in the

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[4] Dr. Steven H. Lamm modified EPA's calculation by dividing EPA's estimates of risk by 35 to estimate the risk resulting from one year's exposure (his Step 2). For this reason, his estimates of risk are not applicable to the prediction of risks accruing to workers exposed indefinitely at current levels, and they need not be considered further here.

general population.[5] Given the long latency period of cancer, this assumption is not obviously conservative and introduces uncertainities of unknown magnitude. Significantly, over 600 of the 748 employees studied by Dr. Infante were alive in 1975 when he made his calculation.

6. *Uncertainties in the form of the dose-response relationship* (see Pet. App. 97a, 124a, 125a, 160a). Once a point on the dose-response relationship is selected from the wide range of possibilities suggested by the observational data, it is necessary to make assumptions about the mathematical form of the relationship before risks at other exposure levels can be estimated. Both Dr. Wilson and EPA assumed for the purposes of calculation that the dose-response relationship would be linear—*i.e.*, that the excess risks attributable to benzene exposure would be directly proportional to the average concentration of benzene to which the person is exposed during his or her lifetime. Although Dr. Wilson claimed that this assumption is "conservative" (A. 164) and "pessimistic" (A. 171), it is easily possible to envision cases in

[5] For the workers in Dr. Infante's cohort who died of leukemia, the interval between the start of employment and death was 2 to 21 years, with an average of 11.5 years (Exh. 2A-271, Table 3). Since the workers who actually died of leukemia are likely to be those with above-average exposure, it is unlikely that the average duration of exposure in the entire cohort could have been that long. The study does not report the average duration of exposure in the entire cohort.

which such an assumption would substantially underestimate risks at low doses.[6]

7. *Uncertainties due to other unrecorded factors* (see Pet. App. 80a-98a, 103a, 117a-118a). Extrapolation of dose-response data from one exposed group to predict risks in another involves the implicit assumption that the groups are similar to each other in all relevant characteristics except the exposure to benzene. Other factors that are known to influence carcinogenic risks include age, sex, smoking habits, and exposure to other chemicals or to radiation. There is little or no information on these factors that would allow comparison of the reference groups with the current workers whose risks are to be calculated. Moreover, Dr. Wilson (A. 171) assumed "conservatively" that for every leukemia induced by benzene "there is one additional cancer death at an unknown site," and for this reason he multiplied the estimate of leukemia risk by a factor of two to obtain estimates of total cancer risk. The basis for his selection of a factor of two is not stated, and it introduces uncertainties of unknown magnitude. It is known, furthermore, that there are additional ben-

[6] An actual example of such a case is presented by recent experimental data on vinyl chloride, which show a dose-response curve rising steeply at low doses and then becoming progressively less steep as the doses were increased. See Scientific Committee of the Food Safety Council, Proposed System for Food Safety Assessment, 16 *Food and Cosmetics Toxicology* (Supp.) 128 (Dec. 1978). The Scientific Committee fitted these data to a mathematical curve which is much more "conservative" at low doses than the linear model used by Dr. Wilson. *Id.* at 115.

zene-related risks other than cancer, such as aplastic anemia which Wilson ignored.

8. *Uncertainties in the number of exposed workers and in their level of exposure* (See Pet. App. 69a, 138a; A. 90). Dr. Wilson (A. 175) based his calculation of risks to the workers presently exposed on a study which estimated that 30,000 workers have 8-hour working day average concentrations above the proposed 1 ppm standard. Dr. Wilson further assumed that these 30,000 workers are now exposed to an average of 3 ppm (A. 176). Although the Secretary regards the estimate of 30,000 workers as reasonable, its accuracy is unknown (see Exh. 5.A at 3-5; Pet. App. 138a). Moreover, Dr. Wilson's assumption that the average exposure level is 3 ppm appears completely arbitrary. It would be more conservative to assume that the average exposure level of the workers is as high as the 10 ppm permitted under the present standard. Thus, the incompleteness of the information on current exposure to benzene introduces uncertainties into the risk estimates of at least a factor of 3.

9. *The total range of uncertainty* (see Pet. App. 160a). The use of the fragmentary existing data on excess cancer incidence in workers formerly exposed to benzene to estimate lifetime risks to workers currently exposed to different levels thus involves a number of assumptions, explicit and implicit, each of which introduces a substantial range of uncertainty into the calculations. Because risk extrapolation is a sequential procedure in which each step utilizes the

results of the preceding steps, these uncertainties expand as the calculation progresses and combine multiplicatively to yield an extremely wide range of uncertainty in the final estimates.

It is difficult to estimate the full magnitude of this range of uncertainty, because information is lacking about the consequences of many of the assumptions. However, as shown above, there is at least an 80-fold variation between the dose-response data in various epidemiologic studies; in addition, there may be uncertainties ranging up to ten-fold resulting from lack of knowledge of the duration of exposure in these studies and up to three-fold resulting from lack of knowledge of current exposure. Since the uncertainties combine multiplicatively, these factors alone introduce uncertainties into the final estimates of risk that may range from one to 2,400. Additional uncertainties of unknown magnitude are introduced by the other factors discussed above, including incomplete follow-up of the reference populations, errors in recording causes of death, fluctuations in exposure, extrapolation of partial-lifetime to full-time risks, possible risks from other diseases, uncertainties in the form of the dose-response and duration-response relationships, age, sex, and synergisms with other risk factors.

So many factors are involved that the range between the lowest and highest reasonable estimates of risks may range into the tens of thousands, if not millions. This range of uncertainty cannot be ignored. Although EPA recognized that its own esti-

mates of general population risks could for these reasons "easily be in error by several orders of magnitude" (A. 25), Dr. Wilson presented only a single estimate of risks and did not discuss uncertainties except to claim that his estimate was conservative and pessimistic. The analysis above shows, to the contrary, that his estimate of risk could easily be too low by many orders of magnitude.

The following "risk assessment," using assumptions different from those used by Dr. Wilson (yet wholly reasonable) illustrates the multiplicative effect of these uncertainties.

1. Rather than reject Dr. Infante's findings, as Dr. Wilson did, our counterexample accepts Dr. Infante's finding that there were 5.6 excess leukemias among the 748 workers whose vital status was studied through 1975. We also assume that the average level of benzene to which workers were actually exposed was 10 ppm (see pages 5a-6a, *supra*).

2. Next, we adjust the number of excess leukemias found by Dr. Infante to take into account uncertainties in his data: (i) we assume that each employee in his cohort was exposed for five years (see pages 6a-7a, *supra*); (ii) Dr. Infante reported 5.6 excess deaths through 1975 when over 600 of the cohort were still alive (see page 8a, *supra*); due to the long latency period, we assume that benzene-induced leukemias will continue to emerge as the cohort ages; we also assume that Dr. Infante missed some leukemias among the 25% of the cohort whose vital status was unknown in 1975 (see page 4a, *supra*),

so that a total of 17 excess leukemias will result over the entire lifetime of the 748 members of the cohort.[7] These adjustments mean that approximately 23 of every 1000 employees exposed for five years at 10 ppm will be expected to die of leukemia as a result of occupational exposure.

3. If we assume that there are 30,000 job positions in the United States now exposed at 10 ppm and that job turnover is such that these positions are filled anew every five years (as we assume was true in the Infante study) then 690 leukemias would eventually result for every five years of exposure at 10 ppm. If there are 60,000 job positions (see page 10a, *supra*), then there would eventually be 1380 leukemias for every five years of occupational exposure. Dr. Wilson predicted 2 cancers every six years (or roughly 1.7 every five years). Thus, simply

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[7] Assuming that the missing 25% of the cohort experienced the same incidence of leukemia as the 75% accounted for, Dr. Infante would have found 9.3 leukemias out of 748 workers. Since only 1.38 leukemias were expected among 748 persons, given their ages through 1975 when the study ended (see Pet. App. 105a), the relative risk of benzene-induced leukemia would be 6.76 (9.3/1.38). The *lifetime* normal risk of leukemia in the general population is 0.39% (A. 20-21) so that in a cohort of 748 persons, 2.92 "normal" leukemias would be expected in their entire lifetimes. Assuming conservatively that the relative risk of benzene-induced leukemias remains constant at 6.96 as the cohort ages, then 19.7 total leukemias (6.76 x 2.92) and 17 excess leukemias (due solely to benzene exposure) would be expected. (Given the long latency period, a conservative extrapolation might well assume even more than 17 excess deaths will appear as the cohort ages, although, for purposes of illustration, we have not made that assumption).

by making different yet reasonable assumptions, we obtain a result about 800 times greater than did Dr. Wilson—illustrating the wide range of uncertainty presented by attempts to quantify the health risk for benzene. (These numbers, moreover, do not include death due to nonmalignant diseases caused by benzene.)

APPENDIX B

14 MAR 1979

Honorable Warren G. Magnuson
Chairman
Committee on Appropriations
United States Senate
Washington, D.C. 20510

Dear Senator Magnuson:

A review of the transcript of our hearings before your Appropriations Committee reveals a misunderstanding on my part in responding to a series of questions regarding cost-benefit analysis. I would like to clarify for the record the agency's position on this issue.

The Occupational Safety and Health Act is primarily prevention-oriented public health legislation which establishes the right of workers to safe and healthful working conditions. Yet the purpose of the Act is not to protect workers by putting employers out of business. Nor is it to cause employers to spend more money than necessary to protect workers. Therefore, the first step in our standard-setting process is to determine on the basis of scientific evidence the level of protection needed to most adequately assure workers' health and safety. Then an assessment of the technological and economic capabilities of affected industries is made. OSHA does not set permissible exposure limits that are technologically infeasible. In addition, the agency seeks to avoid significant economic disruption among affected industries. Both of these factors have been defined by the courts.

In setting standards, OSHA believes that important information is gained from economic studies which indicate the most cost-effective means of providing adequate protection for workers (i.e., achieving a prescribed level of worker protection in the least costly manner). However, such studies are presently somewhat speculative since no reliable means exist for assessing the costs of compliance. Moreover, determining whether the costs of a regulation equal the benefits at the margin cannot be done given existing methodologies and data. For example, present accounting procedures do not readily permit the identification of expenditures for regulation apart from those for capitalization, operation and maintenance. It is also difficult to anticipate, prior to the promulgation of a regulation, its effects on technological and industrial innovation. In some cases American industry has found new and less costly methods of compliance than were anticipated prior to the issuance of a standard.

Likewise, it is difficult to quantify or to express accurately in monetary terms all the benefits of regulation. Failure to reduce workplace hazards results in enormous costs in terms of workers' compensation, disability, medical expenses and health insurance, lost productivity, and worker turnover, but it is not feasible at this time to make a reasonable association between types of accidents or illnesses and subsequent costs. Moreover, some benefits such as decreased pain and suffering, and a better community and family life, can never be quantified.

OSHA is concerned about the effects of its regulations on the allocation of resources in the private sector. With this in mind, the agency has committed itself to a substantial upgrading of pre-regulation analyses. More effective analytical methods and improved data bases are now being developed. However, OSHA is also concerned that economic considerations not be the primary basis for decision-making. We do not believe that workers should be viewed as "human capital." They are human beings with non-quantifiable value, personal needs and feelings. Their health should not be determined by the outcome of a mathematical equation. OSHA therefore favors the use of a "cost effectiveness" approach to setting standards. That is, the agency examines alternative means for achieving prescribed levels of worker protection.

In summary, OSHA will continue to improve the feasibility analyses which accompany new standards. An examination of recent regulations (e.g., cotton dust and lead) reveals a significant improvement in this area over the last several years. However, we do not believe that a rigid cost-benefit formula should be utilized in the standard-setting process. Moreover, incremental cost-benefit analysis is far too theoretical to be applicable, given the limitations of existing methodologies and data bases. If such data and analytical techniques existed, we are confident the evidence would show that in the long run the costs of OSHA regulations are fully justified in terms of health, equity and economic efficiency.

I hope this statement will clarify OSHA's position on the use of cost-benefit analysis in setting health and safety standards. Given the strong public and Congressional interest in this issue, I believe it would be a useful contribution to insert this letter into the record of OSHA's appropriations hearings of February 22, 1979.

Sincerely,

Eula Bingham
Assistant Secretary
Occupational Safety and Health

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FOR ARGUMENT

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Supreme Court of the United States

October Term, 1979

No. 78-911

INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*,
Respondents.

No. 78-1036

RAY MARSHALL, SECRETARY OF LABOR,
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

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IN THE

Supreme Court of the United States

October Term, 1979

No. 78-911

INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*,
Respondents.

No. 78-1036

RAY MARSHALL, SECRETARY OF LABOR,
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

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REPLY BRIEF FOR PETITIONER INDUSTRIAL UNION DEPARTMENT, AFL-CIO

Introduction

The briefs of the industry respondents and the *amici* supporting their position (these respondents and *amici* shall hereinafter be referred to collectively as "industry") pay lip service to sustaining the lower court's statutory analysis. In Part I, *infra*, we respond to such efforts as industry makes in this direction.

The burden of industry's submissions is, however, that this case involves a regulation designed to eliminate a "*de minimis* health risk."; [1] and that "benzene exposures of

[1] Brief for Respondents (hereinafter cited as "API Br.") at 29.

10 ppm or less are unlikely to lead to any leukemia *at all.* . . ."[2] In Part II, *infra*, we show that this depiction is contrary to findings of fact made by the Secretary based on substantial evidence in the record before him. The Secretary found, based on substantial record evidence, that, absent the standard at issue here, over 30,000 workers will be exposed to unsafe levels of a carcinogenic substance, benzene, every day they go to work. In the proceedings before the Secretary, industry offered the data and other evidence it now cites to this Court to show that such exposures—between 10 ppm and 1 ppm of benzene—are safe or of *de minimis* consequence; the Secretary found, however, that industry's evidence did not support that conclusion.

I.

Industry's argument in support of the court of appeals' holding that "the Secretary cannot promulgate an occupational health standard without finding a 'reasonable[] . . . relationship between expected costs and benefits' " is a set of variations on the theme that "[u]nlike the Endangered Species Act of 1973, or the Delaney Clause of the Food, Drug, and Cosmetic Act, the OSH Act aims at relative rather than absolute protection." (API Br. 28.) We agree that OSHA does not require "absolute protection." But that undisputed proposition does not justify the lower court's holding. For Congress in different statutes has adopted a variety of non-absolutist approaches to protecting health and safety, some of which require a balancing of costs and benefits and others of which do not.[3] The protection that the Secretary is to provide to workers against toxic substances, and the factors which the Secretary must consider in promulgating a standard for exposure to such substances, must be ascertained from the langauge of OSHA and its legislative history. "The question . . . is not what a court thinks is generally appropriate to the regulatory process; it is what Congress intended for

[2] *Id.* at 16 (emphasis in original).

[3] We survey these statutes in Addendum A.

these regulations." *E. I. duPont de Nemours & Co.* v. *Train*, 430 U.S. 112, 138 (1977). Cf. *Vermont Yankee Nuclear Power Corp.* v. *NRDC*, 435 U.S. 519 (1978).

1. Industry emphasizes that the "key" to our case is "the first sentence of Section 6(b)(5)." (API Br. 11). We do indeed contend that this case is governed by that sentence:

> The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.

We do so because the language and history of that sentence demonstrate that its office is to establish the extent and limit of the Secretary's authority to regulate exposure to toxic substances.

The Senate's final act prior to passing S.2193 was to rewrite that sentence. The language of § 2(b) and § 3(8)—the other provisions cited by industry to support the argument that the Act is "relative" not "absolute"—had already been settled.[4] Yet, Senator Dominick, the Nixon Administration's spokesman on the Act, continued to insist that the first sentence of § 6(b)(5) as reported out by Committee—"[t]he Secretary, in promulgating standards under this subsection, shall set the standard which most adequately and feasibly assures, on the basis of the best available evidence, that no employee will suffer any impairment of health or functional capacity, or diminished life expectancy even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life" (Leg. Hist. 242)—was defective in that:

[4] See IUD Br. at 27-33; Fed. Parties Br. at 42-48; and Fed. Parties Reply Br. at 19-21 for the arguments showing that these provisions considered alone do not support Industry's position.

> Any administrator responsible for enforcing the statute will be faced with an impossible choice. Either he must forbid employment in all occupations where there is any risk of injury, even if the technical state of the art could not remove the hazard, or he must ignore the mandate of Congress. . . .
>
> The confusion inherent in this provision will, in my opinion, render it no more than a hortatory admonition to the Secretary to fulfill his responsibilities under the act. * * *
>
> In trying to make this bill more palatable there is no point in putting in criteria which cannot be met. [Leg. Hist. 481-482].

The debate that ensued makes it plain that all concerned understood that the language of the first sentence of § 6(b)(5) would set the extent of the Secretary's authority to regulate toxic substances.

The modification of that sentence "agreeable to all" adopted at the conclusion of that debate solved the problem Senator Dominick had identified, as he stated:

> Unfortunately, we had language providing that anyone would be assured that no one would have a hazard, . . . no one would have any problem for the rest of his working life.
>
> It was an unrealistic standard. [Leg. Hist. 502].

The statutory words chosen, on their face, state that the Secretary is to set levels of protection possible to achieve, not those that are perfect in theory but impossible of achievement.[5] And, that reading of the language is consistent with Senator Dominick's earlier statement of his conception of the proper role of the Secretary in setting standards:

> The duty to set standards and produce criteria for standards implies that the criteria and the standards will be as effective as possible; not that they will produce a perfect environment. No human effort can produce a perfect environment no matter how hard we try. [Leg. Hist. 376.]

There is not a word in the debate suggesting that the Senate intended to require the Secretary to balance costs and benefits.[6] Given that the term "feasibility" does not in common parlance connote a cost-benefit evaluation, and that Congress has in numerous instances treated feasibility and cost-benefit evaluation as discrete concepts, "the silence of [Congress] . . . is pregnant with significance." Cf. *Labor Board* v. *Fruit Packers*, 377 U.S. 58, 66-67 (1964).[7]

2. It is inherently unlikely that the second and third sentences of § 6(b)(5), which were adopted in Committee, inform a proper understanding of the amendment to the first sentence, which was adopted on the Senate floor to clarify what the Committee bill meant. And in fact, the latter two sentences do not alter the substantive criteria for toxic substance standards contained in the first sentence; those sentences merely set forth the types of evidence the Secretary is to employ in carrying out the mandate of the first sentence—types of evidence which include not only "research, demonstrations, [and] experiments," but also "such other information as may be appropriate."

The House, whose bill did not set forth any criteria governing the Secretary's standard-setting authority, ac-

[5] For a more complete discussion of the legislative history of the first sentence of §6(b)(5), see our opening brief at pp. 13-23. Industry, rather than focus on this critical point in the genesis of §6(b)(5), contends that Congress' intention in using the word "feasible" should instead be discerned from a statement which accompanied the introduction of the Administration's original proposed occupational safety and health bill in a prior Congress. API Br. at 42-43, 9b. Industry mistakenly attributes that statement to Senator Javits, misconstrues its import, and ignores Senator Javits' reservations as to the merit of the Administration bill. See Fed. Parties Reply Br. at 22-23, n. 17.

[6] See Fed. Parties Reply Br. at 24-26 for a demonstration of the irrelevance to the issue here of the substitution of the word "material" for "any" which occurred in the same amendment to §6(b)(5) described in the text.

[7] For examples of statutes in which Congress has treated feasibility and cost-benefit evaluation as discrete concepts see Addendum A to this brief.

cepted §6(b)(5) as passed by the Senate. To be sure as industry points out, the Conferees altered the Senate bill by adopting §6(f) which provides that the Secretary's findings are to be supported by "substantial evidence on the record as a whole." The Conferees did not suggest that §6(f) modifies the Act's substantive provisions and we cannot discern the logic of industry's implication that it does so.

3. It is decisive that industry's argument that the Secretary is required to balance costs and benefits lacks a statutory predicate. But out of caution we pause to note the defects in industry's policy justification for its position—*viz.* that such an inquiry must be undertaken so that the

> finite * * * * societal resources that can be devoted to these health and safety risks * * * [are] allocate[d] . . . where they can be expected to do the most good.[8]

The "logic" of this justification requires that the Secretary, before he can promulgate a standard to protect employees against any health hazard, must inventory all other hazards possibly faced by those employees and then compare the relative costs and benefits of the proposed standard with the costs and benefits of regulating each of the other possible hazards. And industry would read the Act to require the Secretary to embark on that task despite the recognition by the sponsors that:

> In the field of occupational health * * * [there is a] lack of information and records, * * *
>
> * * * [M]aterials long in industrial use are only now being discovered to have toxic effects. * * * [T]echnological advances and new processes in American industry have brought numerous new hazards to the workplace. * * * It is estimated that every 20 minutes a new and potentially toxic chemical is introduced into industry. New processes and new sources of energy present occupational health problems of unprecedented complexity.

[8] API Br. at 29, 27, 73; see also id. at 5, 18-20, 25, 32-33, 35, 58-59, 63, 66, 72, 78, 80; and Addendum C at 2c, 7c. See also Brief for *Amicus* Chamber of Commerce (hereinafter "Chamber Br.").

> Recent scientific knowledge points to hitherto unsuspected cause-and-effect relationships between occupational exposures and many of the so-called chronic diseases—cancer, respiratory ailments, allergies, heart disease, and others.[9]

Nevertheless under industry's construct, to do anything the Secretary would have to investigate and evaluate everything. This in the name of "common sense" and "pragmatism." See API Br. 5, 29.

II.

In our opening brief, at 8-11, we set forth the Secretary's nine critical findings which form the predicate for the promulgation of the benzene standard. None of those findings was upset by the court below. Those findings negate any contention that the health risk sought to be reduced by the standard is either non-existent or *de minimis*: exposure to airborne benzene causes leukemia and other serious and sometimes fatal diseases; hundreds of employees in this country have died of leukemia from occupational exposure to airborne benzene; without the standard, over 30,000 employees in this country will regularly be exposed to airborne benzene at their workplaces at levels in excess of 1 ppm; there is no level of exposure to benzene which can be considered safe in terms of benzene's leukemogenic effect; a decrease in the exposure level to benzene will result in a decreased risk of leukemia; and, there is no way to quantify the number of leukemia deaths that would result if the standard is not put into effect, let alone to conclude that that number would be zero or *de minimis*.

In making these findings, the Secretary considered evidence submitted by industry in support of the contention that there is no health risk posed by regular exposure to benzene at levels of 10 ppm and below. The Secretary, after reviewing the entire record, including the cross-examination of industry's witnesses, found that industry's evidence does

[9] S. Rep. No. 91-1282, 91st Cong., 2d Sess. 2-3 (1970), Leg. Hist. 142-143.

not support its contention. In this Court, industry in effect resubmits that same evidence. First, industry refuses to accept that the Secretary found, based on ample record evidence, that there is no safe level of exposure to airborne benzene. Second, industry ignores that the Secretary found, again based on ample record evidence, that there is no way to quantify the number of lives that will be saved by the standard. Given the weight industry places on the assertion that the standard does not add to the protection afforded the employees covered, we turn now to the substantial evidence that supports the Secretary's contrary conclusion.

A. The Secretary's finding that there is no level of exposure to benzene which can be considered safe is supported by substantial evidence in the record.

In the proceeding before the Secretary, it was undisputed that exposure to airborne benzene causes leukemia; studies had reported the incidence of leukemia among workers exposed to high levels of benzene for varying lengths of time to be as much as a twenty times greater than the incidence among the general population. Pet. App. 100a. There was considerable dispute, however, on the question whether a safe level of exposure to benzene could be identified. A number of eminent medical scientists—*inter alia*, Dr. Muzaffer Aksoy of Instanbul University (Ex. 60 at 12-13; Tr. 148-149); Dr. Marvin Sakol (Tr. 328); Dr. Bernard Goldstein of the New York University Medical Center (Ex. 75 at 2; Tr. 351-352); Dr. Peter Infante of the National Institute for Occupational Safety and Health ("NIOSH") (Tr. 895); and Dr. Robert Laigo of NIOSH (Tr. 1229)—testified that, on the basis of the current state of medical and scientific knowledge relating to benzene, exposure to benzene must be considered unsafe at all levels. NIOSH, the research arm created by the Act to provide the Secretary expert assistance in standard setting,[10] also went on record in support of the proposition that no level of exposure to benzene can be considered safe. Ex. 2.5 at 6; Tr. 745-746.[11] Indeed, on the basis of its analysis of the scientific evidence concerning the risks posed by benzene, NIOSH had "strongly recommend[ed]" in 1976 that the Secretary immediately promulgate an emergency temporary standard reducing permissible exposures to 1 ppm. Pet. App. 72a; Ex. 2-6 at 1; see also Ex. 2-5 at 1, 6.

[10] Section 22(a) of the Act, 29 U.S.C. § 671(a).

In view of this testimony, industry's assertion that the Secretary's no-safe-level finding rested solely on a "regulatory 'policy assumption,'" rather than on a "factual basis" is wrong.[12] While the issue could not be resolved by empirical evidence, the expert scientific testimony upon which the Secretary relied constitutes substantial evidence in support of his determination. As this Court has repeatedly held,

> well-reasoned expert testimony—based on what is known and uncontradicted by empirical evidence—may in and of itself be "substantial evidence" when first-hand evidence on the question . . . is unavailable. This proposition has been so long accepted, . . . that we do not consider it fairly in dispute.

FPC v. Florida Power & Light Co., 404 U.S. 453, 464-466 (1972). The Court in that case went on to quote from an opinion by Judge Parker in *United States ex rel. Chapman v. FPC*, 191 F.2d 796, 808 (4th Cir. 1951), aff'd, 345 U.S. 153 (1953), the following passage which has application here as well:

> The [substantial-evidence] rule is no different because

[11] The Secretary's no-safe-level determination was also supported by extensive record evidence regarding carcinogens in general. See, e.g., the Report to the Surgeon General by the Ad Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens of the National Cancer Institute (Ex. 272 at 1); the views of the Committee on Public Information in the Prevention of Occupational Cancer of the National Academy of Sciences (reported in Ex. 76 at 4); and the testimony of Dr. Herman Kraybill of the National Cancer Institute (Tr. 1210) and of Dr. Charles Shaw, a cancer researcher at the M. D. Anderson Hospital and Tumor Institute (Tr. 140). See also Ex. 97 at 55.

[12] API Br. at 16, and n. 38.

the questions involve matters of scientific knowledge and the evidence consists largely of the opinion of experts. The court may not, for that reason, ignore the conclusions of the experts and the Commission and put itself in the absurd position of substituting its judgment for theirs on controverted matters of [science]. It is in just such matters that the findings of the Commission, because of its experience and the assistance of its technical staff, should be accorded the greatest weight and the courts should be hesitant to substitute their judgment for that of the Commission.[13]

B. The Secretary's finding that there is no way to estimate the number of lives that will be saved by the standard is supported by substantial evidence in the record.

There is no direct empirical data documenting the extent of the risk of leukemia for employees exposed to airborne

[13] Industry appears to suggest that by eliminating language which would have allowed standards to be issued on the basis of "views and arguments," Congress meant to preclude the Secretary from relying on expert scientific opinions. But industry misapprehends the nature of Congress' concern regarding that language.

The "views and arguments" provision appeared in the Daniels bill as reported out of the House Committee (Leg. Hist. 728-730), and in the Williams bill (S. 2193) as originally introduced (Leg. Hist. 6-7). It stated: "Upon the entire record before him, including . . . any evidence, data views and arguments submitted in connection with the hearing, the Secretary shall . . . issue a rule. . . ." (Leg. Hist. 7, 730). The provision was deleted from the Williams bill by the Senate Committee, without discussion, see S. Rep. No. 91-1282, 91st Cong., 2d Sess. (1970), Leg. Hist. 141 *et seq.* In lieu of the Daniels bill, the House passed the Steiger-Sikes substitute bill, which did not specify the basis upon which standards were to be promulgated, but which listed "views or arguments" among the matters which interested parties could submit to the standard-setting agency. See Leg. Hist. 1120-1122. The Conference Committee adopted the Senate provision without any discussion of the "views and arguments" language contained in the House provision. See H.R. Rep. No. 91-1765, 91st Cong., 2d Sess. 35 (1970), Leg. Hist. 1188. Only one statement in the legislative history cited by industry actually bears on the "views and arguments" provision; it is found in the "Additional Minority Views" expressed in the House Report. See H.R. Rep. No. 91-2191, 91st Cong., 2d Sess. 53, 54 (1970), Leg. Hist. 883, 884. That statement refutes industry's theory as to why the provision was revised.

Under the heading "Full Protection of the Administrative Procedures Act Denied," the authors of the minority views stated that by allowing standards to be based "upon 'views and arguments' rather than solely on probative evidence," the Committee bill "depart[ed] from the provisions of the APA" and "deviat[ed] from regular and fair procedures." *Ibid.* They protested that "[t]he requirements that administrative decisions be based upon facts and sound reasons mean little when a loophole of this type is included in a statute." *Ibid.*

As we have shown in the text, it has long been settled that an agency subject to a substantial evidence test may properly base its regulations on expert scientific opinions. It is therefore plain that the authors of the minority views were not suggesting that the Secretary could not consider evidence of this sort. Rather, the fair reading is that the authors of the minority views feared that the unusual reference to "views and arguments" in the Committee bill would permit the Secretary to base a standard on nothing more than the mere arguments of interested parties.

benzene at or below the level of 10 ppm. The absence of such direct data is not attributable to any failure on the Secretary's part. The latency period for benzene-induced leukemia can span a period of twenty years or more. Pet. App. 182a. Consequently, a valid study of actual case histories (an epidemiologic study) must examine benzene exposures which occurred many years in the past. As the Secretary explained, "it is extremely difficult to reconstruct and define employee exposures retrospectively." Pet. App. 182a. Moreover, exposures from that long ago were in general "most certainly . . . at higher concentrations than present levels." *Ibid.* See Tr. 2556-2557, 2667. Thus, the Secretary found that there was an absence "of an adequate size cohort of workers exposed to benzene less than 10 ppm and who have been followed for an adequate amount of time." Pet. App. 182a-183a.[14]

Lacking any direct data showing actual experience with

[14] See Addendum B to this brief for a discussion of the evidence supporting the Secretary's rejection of industry's contention that certain epidemiologic studies demonstrate an absence of leukemia risk from benzene exposures of 10 ppm or below.

benzene exposures at 10 ppm and below, the Secretary considered whether he could utilize the results of studies in the record involving exposure to higher concentrations of benzene to estimate how many lives would be at risk at exposure levels of 10 ppm and below. The Secretary concluded that "there does not exist an adequate scientific basis for establishing the quantitative dose-response relationship between exposure to benzene and the induction of leukemia and other blood diseases." Pet. App. 160a. He reached that conclusion for two reasons.

First, the predicate for estimating unknown quantities from known quantities is that there must first be a known quantity. But the Secretary found "uncertainty in . . . the actual magnitude of expected deaths" attributable to any level of exposure. Pet. App. 160a. The available epidemiologic data showing the leukemogenic effects of benzene exposures at levels thought to be in excess of 10 ppm do not show the *level* and *duration* of exposure of the cases studied, and the data understate, to a degree which cannot be determined, the number of leukemia deaths resulting from such exposure.[15] As Dr. Herman Kraybill of the National Cancer Institute testified, he along with other scientists had attempted to develop a dose-response curve for benzene, but had abandoned the effort due to the lack of necessary data. Tr. 760-761, 776. In Dr. Kraybill's words (Tr. 760-761):

> . . . [W]e like to estimate risk factors. This has been done, as many of you recall, with vinyl chloride several years ago.
>
> . . . [T]o estimate the risk factors on experimental data, . . . presupposes [that] you have good toxicity data. When I say toxicity data, I mean good dose-response data[. For] vinyl chloride . . . indeed we did have that.
>
> But with benzene, it appeared that we didn't have this situation, so therefore, most of us gave up. . . .
>
> • • • •
>
> With benezene, we sort of struck out.[16]

Second, even if the existing studies could have provided a starting point, the Secretary found that there is no satisfactory theory of extrapolation from known carcinogenic effects of a substance at high exposure levels to projected carcinogenic effects of the substance at lower exposure levels. Pet. App. 160a. As Dr. Richard Wilson, upon whose testimony industry places such great reliance, grudgingly acknowledged (App. 93):

> It is conceivable, I suppose, that any dose-response curve is possible. . . . It would be a rather unusual, almost I think, revolutionary contribution to the literature on cancer to have a dose-response curve on cancer.

See also, McGarity, *Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA*, 67 Geo.L.J. 729, 736 n. 27 (1979); Addendum C at 8c-9c.[17]

In the face of these findings, industry continues to cite

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[15] Further, the Secretary found that genetic, environmental and other factors produce variations in the susceptibility of individuals to benzene-induced leukemia. Pet. App. 184a. Consequently, there is no assurance that the incidence of benzene-leukemia found in any study of a particular group of employees accurately represents the incidence which would occur in the general population.

[16] Dr. Bernard Goldstein of the New York University Medical Center testified to the same effect (Tr. 360):

> We don't have information that I would say would be good to give us a relation between any levels of benzene and leukemia. I just don't think that one can take this type of data and say that, "Well, let's see, we got nothing at 50; we got something at 40; we got nothing at 60." The literature just is not conducive to that type of analysis.

The testimony of Dr. Charles Shaw of the M. D. Anderson Hospital and Tumor Institute was in accord (Tr. 415). See also the testimony of Dr. Infante, Tr. 1055-1056, 1156.

[17] Industry nevertheless maintains that a meaningful "risk assessment" could be prepared by making "conservative assumptions" at each point of uncertainty, so as to arrive at an "upper-bound" estimate of the risk. See API Br. at 20; Chamber Br. at

as if it were gospel an extrapolation submitted by Dr. Wilson based on selected epidemiologic data in the record. It is upon this extrapolation that industry largely bases its claim that the health risk regulated by the Secretary is non-existent or *de minimis*. In addition to the Secretary's general findings that such extrapolations are invalid, the Secretary specifically considered and rejected Dr. Wilson's extrapolation. Pet. App. 161a-162a. We show in Addendum C to this brief the particular factors which support the Secretary's rejection of Dr. Wilson's analysis.

10-12. But as we show more fully in Addendum C, given the gaps in the existing data, the uncertainties which confront any effort to estimate the extent of the risks posed by low-level benzene exposures are so great that the range of possible assumptions is literally infinite; "[t]he choice of assumptions under these conditions of uncertainty transcends the domain of science." Lovins, *Cost-Risk-Benefit Assessments in Energy Policy*, 45 Geo. Wash. L. Rev. 911, 924 (1977). Even if the range of uncertainty were narrower, industry's notion that truly "conservative" assumptions can be identified is mistaken. "Conservative assessments embody value judgments in a not clearly identifiable way * * * * [The] problem with the conservatism argument is that there is no place at which it can stop * * * * In practice of course, people do stop, but then it becomes difficult to understand what they mean by being conservative." Cornfield, *Carcinogenic Risk Assessment*, 198 Science 693, 695-696 (1977).

Industry contends that various public and private bodies have endorsed the use of risk assessments based on "conservative assumptions" in a number of regulatory contexts. But that contention sheds no light on how *this* statute should be construed and administered. However, lest the Court be left with a false impression that unanimity exists with respect to the role of risk assessments in regulatory policy, we note simply that this matter is presently a subject of substantial political debate. See generally Baram, *Regulation of Health, Safety and Environmental Quality and the Use of Cost-Benefit Analysis*, Final Report to the Administrative Conference of the United States, March 1, 1979 at 19-45. For example, a Congressional committee has stated that "[t]he limitations on the usefulness of benefit/cost analysis in the context of health, safety, and environmental regulatory decision-making are so severe that they militate against its use altogether." House Committee on Interstate and Foreign Commerce, Subcommittee on Oversight and Investigations, *Federal Regulation and Regulatory Reform*, 95th Cong., 1st Sess. 515 (1976).

C. This case involves a regulation to protect more than 30,000 workers from a risk of potentially great; albeit unknowable, dimensions.

The upshot of the Secretary's findings, based on the best available evidence, is that the leukemia risk posed by employee exposure to benzene at levels of 10 ppm or below is potentially great, albeit unknowable. The Secretary rejected industry's contention that the risk is non-existent or *de minimis;* and the Secretary's assessment of the nature of the risk to which the benzene standard is directed, being firmly grounded in the record evidence, is conclusive. *United States* v. *Bacto-Unidisk*, 394 U.S. 784, 791 (1969).[18]

Industry asserts nevertheless that the court below adopted its characterization of the health risk at issue here. The Secretary in his Statement said: "While the actual estimation of the number of cancers to be prevented [by the standard] is highly uncertain, the evidence shows that the number may be appreciable." Pet. App. 160a. The court of appeals, in considering whether the Secretary had demonstrated sufficient benefits from the standard to satisfy a cost-benefit evaluation, stated as follows (Pet. App. 17a, 18a):

> OSHA merely assumed that benefits from the reduction "may be appreciable."
>
> • • •
>
> This justification is deficient in one crucial way: substantial evidence does not support OSHA's conclusion that benefits are *likely* to be appreciable. Without an estimate of benefits supported by substantial evidence, OSHA is unable to justify a finding that the benefits to be realized from the standard bear a reasonable relationship to its one-half billion dollar price tag.

(Emphasis added).

[18] Cf. also *Radio Corp.* v. *United States*, 314 U.S. 412, 419-420 (1951); *Permian Basin Area Rate Cases*, 390 U.S. 747, 766-767 (1968).

Industry implies that the court of appeals thus found that the benefits of the standard are non-existent or *de minimis*. But in context the court's words bear a quite different meaning. The court's conclusion was not that the benefits of the standard are in fact non-existent or *de minimis*, but that the Secretary had not demonstrated by what the court deemed appropriate evidence that the benefits of the standard would justify its costs. As the court went on to explain (Pet. App. 18a-19a):

> Th[e] finding and deduction [that the standard will result in some benefit], however, does not yield the conclusion that measurable benefits will result, and OSHA is unable to point to any *studies or projections* supporting such a finding. . . . The lack of substantial evidence of discernible benefits is highlighted when one considers that OSHA is unable to point to any *empirical evidence* documenting a leukemia risk at 10 ppm even though that has been the permissible exposure limit since 1971. OSHA's assertion that benefits from reducing the permissible exposure limit from 10 ppm to 1 ppm are likely to be appreciable, an assumption based only on inferences drawn from studies involving much higher exposure levels *rather than on studies involving these levels or sound statistical projections from the high-level studies,* does not satisfy the reasonably necessary requirement limiting OSHA's action.

(Emphasis added). See also Pet. App. 33a.

The court, then, did not overturn the Secretary's conclusion that the health risk addressed by the standard is potentially great, albeit unknowable—i.e., that the "number of cancers to be prevented" though "uncertain . . . may be appreciable." Pet. App. 160a. Rather, the court construed the Act to foreclose the Secretary from issuing a regulation to protect employees from that risk until empirical "studies or projections" establish that the risk is in fact of sufficient magnitude to justify the costs of the standard. In the court's words, "[u]ntil such estimates are possible, OSHA does not have sufficient information" to regulate. Pet. App. 21a.

As we have shown, the Secretary found that the existing epidemiologic data are inadequate to serve as a basis for an extrapolation of the leukemia risk at benzene exposure levels of 10 ppm or below. There is no basis in the record for supposing that this inadequacy may be overcome by any means short of awaiting the experience of long-term exposures to benzene at the levels—i.e., 10 ppm and below—permitted by the standard which the Secretary sought to replace. Thus, notwithstanding the court's disclaimer, it may well be that the consequence of its ruling is that "OSHA must wait until deaths occur as a result of exposure at levels below 10 ppm before it may validly promulgate a standard reducing the permissible exposure limit." Pet. App. 20a. See our opening brief at 27-28, nn. 27-28.

The court said that the Secretary "must regulate on the basis of what is known rather than on the basis of what is unknown." Pet. App. 20a. So, indeed, he must. But as Socrates taught long ago, the highest knowledge is knowing the limits of our own knowledge. That lesson has special force where, as here, the inquiry is at the "frontiers of scientific knowledge." *IUD* v. *Hodgson*, 499 F.2d 467, 474 (D.C. Cir. 1974). The Secretary's instant determination was based not, as the court of appeals would have it, on arbitrary "assumptions," but, in precise accord with the third sentence of §6(b)(5), on the best scientific evidence available—evidence concerning both what is known and what is not known about benzene as a carcinogen. "Under the command of OSHA, it remains the duty of the Secretary to act to protect the workingman, and to act even in circumstances where existing methodology or research is deficient." *Society of the Plastics Indus., Inc.* v. *OSHA*, 509 F.2d 1301, 1308 (2d Cir. 1974), *cert. denied*, 421 U.S. 992 (1975).

CONCLUSION

For the reasons stated herein and in our opening brief, the decision of the Fifth Circuit should be reversed insofar as it invalidates the reduction in the permissible exposure limit and the provisions related thereto.

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ADDENDUM A

A Survey of "Non-Absolutist" Statutory Approaches to Protecting Health and Safety

Balancing of costs and benefits is expressly required by several regulatory statutes. An early example is the Flood Control Act of 1936, 33 U.S.C. § 701(a): "[T]he Federal Government should improve or participate in the improvement of navigable waters . . . for flood-control purposes if the benefits to whomsoever they accrue are in excess of the estimated costs and if the lives and social security of people are otherwise adversely affected." More recent examples include two statutes in which Congress has provided that in addition to being "feasible," regulations promulgated under the statute should reflect a balancing of costs and benefits. The Outer Continental Shelf Lands Act Amendments of 1978, 43 U.S.C. § 1347(b), provide that offshore drilling operations shall use "the best available and safest technologies which the Secretary determines to be economically feasible, . . . except where the Secretary determines that the incremental benefits are clearly insufficient to justify the incremental costs of utilizing such technologies." The Energy Policy and Conservation Act of 1975, 42 U.S.C. § 6295 (a) (4) (D), provides that energy efficiency standards promulgated for certain products must not only be "economically feasible," but must, in addition, be such that "the savings in operating costs . . . outweigh" the adverse effects of the standard.

In several instances, Congress has required some form of cost-benefit balancing with respect to the promulgation of certain regulations under a statute, while requiring other regulations under the same statute to be developed without regard to any such balancing, albeit with some consideration of costs. A good example is the Federal Water Pollution Control Act Amendments of 1972, as amended, 33 U.S.C. § 1251 *et seq.*

That statute specifies that in setting effluent limitations to be achieved by 1977, the Environmental Protection

Agency ("EPA") is to require the use of the "best practicable control technology currently available (§ 1311 (b)(1)), and the statute further provides that EPA's "assessment of [that] technology shall include consideration of the total cost of application of technology in relation to the effluent reduction benefits to be achieved from that application. . . ." (§ 1314 (b)(1)(B)). The latter requirement entails a "limited cost-benefit analysis"— a "balancing test between total cost and effluent reduction benefits [which] is intended to limit the application of technology only where the additional degree of effluent reduction is wholly out of proportion to the costs of achieving such marginal level of reduction. . . ." 118 Cong. Rec. 33696 (1972), discussed in *E. I. duPont de Nemours & Co.* v. *Train*, 430 U.S. 112, 129-130 (1977).

On the other hand, the 1972 Amendments provide that effluent limitations to be attained by 1983 should be based on "the best available technology economically achieveable" (as amended, § 1311 (b)(2)(A)), and under that provision, while costs are to be considered, "no balancing test will be required." 118 Cong. Rec. 33696 (1972). See *Weyerhaeuser Corp.* v. *Costle*, 590 F.2d 1011, 1044-1046 (D.C. Cir. 1978).

The amendments also authorize EPA to set more stringent effluent limitations for particular sources of pollution where the generally mandated levels will not achieve the required standard of water quality in a particular setting; but before so doing the Administrator must conduct a public hearing to assess the "economic and social" costs and benefits involved (33 U.S.C. § 1312 (b)(1)), and the more stringent limitations cannot be applied against any person who demonstrates at that hearing that "there is no reasonable relationship between the economic and social costs and the benefits to be obtained. . . ." 33 U.S.C. § 1312 (b)(2).

Similarly, the Clean Water Act of 1977, 33 U.S.C. § 1251 *et seq.*, which established new criteria for the regulation of "conventional pollutants," requires that in setting effluent limitations for such substances EPA shall consider "the reasonableness of the relationship between the costs of attaining a reduction in effluents and the effluent reduction benefits derived. . . ." 33 U.S.C. § 1314 (b)(4)(B).

Another statute which requires cost-benefit evaluations for some regulations but not others is the Clean Air Act Amendments of 1970, as amended, 42 U.S.C. § 7401 *et seq.*, which were passed the same week as OSHA. In that statute, the provision which authorizes EPA to prohibit the manufacture or sale of a fuel or fuel additive that significantly impairs an emission control device expressly requires EPA to perform "a cost benefit analysis" (42 U.S.C. §7545f-6c(c)(2)(B), while the provision which authorizes the prohibition of a fuel or additive that would "endanger the public health or welfare" contains no such requirement (42 U.S.C. § 7545f-6c (c)(2)(A)).

Another "non-absolutist" approach to health and safety regulation, requiring a particular form of cost-benefit balancing, has been adopted by Congress in the several statutes which are based on the concept of "unreasonable risk."

One of the first "unreasonable risk" provisions is contained in the National Traffic and Motor Vehicle Safety Act of 1966, as amended, 15 U.S.C. §1391(1). "As the Senate hearings make clear, the word 'unreasonable' was placed in the bill deliberately, to signify a 'common-sense' balancing of safety benefits and economic cost." *United States* v. *General Motors Corp.*, 518 F.2d 420, 435 (D.C. Cir. 1975). See S.Rep. No. 89-1301, 89th Cong., 2d Sess. 6 (1966).

The year before OSHA was enacted, Congress incorporated an "unreasonable risk" requirement in the Child Protection and Toy Safety Act of 1969, as amended, 15 U.S.C. § 1261(s). The provision was included so as to require consideration of "such factors as the utility of the object, the degree of danger it presents, and the feasibility of designing out that danger." S.Rep. No. 91-237, 91st Cong., 1st Sess. 7 (1969). See generally *Forester* v. *CPSC*, 559 F.2d 774, 789 (D.C. Cir. 1977).

Two years after OSHA was enacted, Congress adopted an "unreasonable risk" requirement in two more statutes. In incorporating that concept in the Consumer Product Safety Act of 1972, Congress stated:

> Protection against unreasonable risks is central to many Federal and State safety statutes and the courts have had broad experience in interpreting the term's meaning and application. It is generally expected that the determination of unreasonable hazard will involve the Commission in balancing the probability that risk will result in harm and the gravity of such harm against the effect on the product's utility, cost and availability to the consumer.

H.R. Rep. No. 92-1153, 92d Cong., 2d Sess. 33 (1972). See also S. Rep. No. 92-749, 92d Cong., 2d Sess. 6, 14-15 (1972). We discussed the pertinent provisions of the Consumer Product Safety Act in our opening brief at pp. 30-33. Similarly, in the Federal Environmental Pesticide Control Act of 1972, as amended, 7 U.S.C. § 136(bb), Congress defined the term "unreasonable adverse effects on the environment" to mean "an unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." The EPA may regulate a pesticide only to the extent that the pesticide entails such "unreasonable adverse effects." See 7 U.S.C. §§ 136a(c)(5)(C), (D), 136a(c)(7), (8), 136a(d), 136d(b). This explicitly requires a balancing of costs and benefits. See *Environmental Defense Fund* v. *EPA*, 548 F.2d 998, 1005 (D.C. Cir. 1976).

Recently, Congress enacted yet another statute based on the concept of "unreasonable risk" and explicitly requiring a balancing of costs and benefits: the Toxic Substances Control Act of 1976, 15 U.S.C. § 2605(a), (c)(1).

Finally, the provisions of the Federal Food, Drug, and Cosmetic Act concerning human and animal drugs, 21 U.S.C. §§ 321(p)(1), 360b, illustrate an altogether different "non-absolutist" approach. In determining whether a human drug is "safe" the Food and Drug Administration

("FDA") must assess whether "the expected therapeutic gain [from the drug] justifies the risk entailed by its use." *United States* v. *Rutherford*, —— U.S. ——, 47 U.S.L.W. 4724, 4727 (June 8, 1979). That is to say, a drug is "safe" only if its curative benefits outweigh its side effects. But while the statute requires a balancing of *therapeutic* costs and benefits, it does not contemplate a balancing of *economic* costs and benefits. See Decision of the Commissioner in the Matter of Diethylstilbestrol: Withdrawal of Approval of New Animal Drug Applications, 44 Fed. Reg. 54852, 54881-54883 (Sept. 21, 1979). On the other hand, the provisions of the Food, Drug, and Cosmetic Act which authorize FDA to set "tolerances" for certain hazardous substances (e.g., 21 U.S.C. §§ 346, 346a, 348(c)(4)(A), (B)) may contemplate some form of economic cost-benefit balancing. *Id.* at 54881-54882.

ADDENDUM B

An Analysis of the Basis for the Secretary's Rejection of Industry's Contention That Epidemologic Studies Have Shown Benzene to Be Safe at Low Levels of Exposure

In its attempt to portray the risks arising from exposure to benzene at concentrations of 10 ppm and below as nonexistent or *de minimis*, industry relies on a group of epidemiologic studies which the industry respondents cited first to the Secretary and then to the court below in their effort to demonstrate that a safe "threshold" level of exposure exists for benzene. API Br. at 14-17. See pp. 8-10. of the reply brief, *supra*. The Secretary expressly rejected industry's contentions regarding the conclusions which can be drawn from the studies, and the court of appeals did not upset the Secretary's determinations. Undaunted, industry now offers its theories regarding those studies to this Court, as if those theories were fact.

Industry advances two arguments regarding the epidemiologic data. First, industry claims "it was shown that when benzene exposures were reduced below 100 ppm—*but not eliminated*—the excess incidence of leukemia found in the principal studies cited by OSHA (the reports of Drs. Infante, Aksoy and Vigliani) *ceased to occur.*" API Br. at 14 (emphasis in original). Second, industry asserts that "this [purported] evidence that low-level benzene exposures present no significant risk of leukemia was bolstered by a series of epidemiologic studies of hundreds of thousands of workers exposed to low concentrations of benzene" which, according to industry, "all failed to uncover any excess incidence of leukemia. . . ." API Br. at 14-15. (These latter studies are referred to as the "negative studies.")

In this Addendum, we show that industry's representations regarding the epidemiologic studies—which are "supported" by little more than citations to the arguments presented in the briefs filed by the industry respondents

before the Secretary—seriously distort the facts as found by the Secretary and as established by the record. As we show, the Secretary correctly found that the epidemiologic studies lend no support to industry's contention that the risks posed by worker exposure to benzene at concentrations of 10 ppm and below are nonexistent or *de minimis*.

I. The Aksoy, Vigliani and Infante Studies

Industry maintains that the data assembled by Dr. Aksoy and Dr. Vigliani, which demonstrate a risk of leukemia at certain exposure levels, show that "when benzene exposures were reduced below 100 ppm—*but not eliminated*—the excess of leukemia found in the . . . studies . . . *ceased to occur*" API Br at 14 (emphasis in original). Although industry makes this representation as if it were an undisputed fact, in reality industry's view of the data is directly contrary not only to the findings of the Secretary regarding this data, but to the statements of Dr. Aksoy and Dr. Vigliani as well.

Industry's view of the Aksoy and Vigliani data is premised on the assumption that when the use of high-benzene solvents ceased in the workplaces studied by Drs. Aksoy and Vigliani, the solvents which were substituted continued to contain substantial amounts of benzene. But Dr. Aksoy stated that "[t]he substitutes for benzene in the workplaces studied were analyzed by gas chromatography . . . The results showed that the substitutes contained *no benzene.*" Ex. 60 at 3 (emphasis added). See also Tr. 2567 (testimony of Dr. Irving Tabershaw). Similarly, Dr. Vigliani wrote that no new cases of leukemia were reported in the workplaces he studied after "the replacement of benzene with toulene" (Ex. 2.15 at 125); and the Secretary found that Dr. Vigliani's data demonstrate that "toulene and benzene are '. . . quite different chemical entities from toxicological and pharmacological points of view' and that, 'toulene *free from benzene* can be safely used in industry as a suitable solvent *in replacement of benzene.*'" Pet. App. 101a (emphasis added).

Thus, as the Secretary found, the Aksoy and Vigliani data show that the excess leukemia incidence in the populations in question ended when exposures to benzene had been *eliminated*—not, as industry would have it, when exposures had been reduced to low levels. Pet. App. 100a-102a. The court of appeals did not disagree with that conclusion. See Pet. App. 8a, n. 13.

Industry's interpretation of the Infante study is as far-fetched as its view of the Aksoy and Vigliani studies. Industry makes much of the fact that while Dr. Infante's study found a large excess incidence of leukemia among a group of workers who had been exposed to benzene in the 1940's, a study by University of North Carolina ("UNC") researchers involving workers employed at a later date in one of the Pliofilm operations which had been studied by Dr. Infante did not uncover any excess incidence of leukemia. API Br. at 14, citing Ex. 187.B-13. Industry contends that this divergence results from the fact that exposures in the plant were probably lower during the time period studied by these researchers than during the time period studied by Dr. Infante. But the number of Pliofilm workers studied by UNC was so small that the study involved only 18 deaths from any cause among those workers. Ex. 187.B-13, Table 1, p. 9.[1] In the general population, only about .75 percent of deaths are from leukemia. See Tr. 2791-2792. Consequently, out of 18 deaths in the general population, the predicted number of leukemia deaths would be 0.13. Thus, one would not expect to find a leukemia death among the workers studied by UNC even if those workers were subjected to a risk factor much higher than that of the general population. As Dr. Infante testified with respect to a similar study involving the same plants:

> "[W]hen you are expecting less than one case, and . . . you observe none, . . . to make any kind of scientific

[1] Table 1 shows that 18 deaths due to all causes were observed in "Occupational Title Group 19." Group 19 is the Pliofilm area, see Ex. 187.B-13 at 8, 40.

statement . . . even about absence of risk on those numbers would, to me, be entirely misleading. (Tr. 1079-1080).[2]

II. The "Negative Studies"

Industry asserts that the absence of any "significant" risk of leukemia at low-level benzene exposures was demonstrated at the hearing by "a series of epidemiologic studies of hundreds of thousands of workers exposed to low concentrations of benzene." API Br. at 14-15. But the Secretary analyzed each of those studies and found that because of gross deficiencies in the design of the studies, their results are meaningless. See Pet. App. 107a-112a, 123a-124a, 182a. As we now show, the Secretary's appraisal of the "negative studies" was well-founded.

a) *The Thorpe Study.* Industry places its primary reliance on a study conducted by Dr. John Thorpe, Associate Medical Director of Exxon Corporation. See API Br. at 15-16. But the Secretary found the Thorpe study to be invalid (Pet. App. 110a-111a); and that judgment was supported by the testimony of NIOSH (Tr. 745) and several expert witnesses. See, e.g., Tr. 914, 1200-1201 (Dr. Infante); Tr. 914-915 (Dr. Smith).[3]

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[2] In addition, the UNC study used an extremely inexact method for determining the department in which an employee was deemed to have worked. See Ex. 187.B-13 at 25. As a result, it is entirely possible that many of the workers whom the UNC study assumed had worked in Pliofilm operations had actually spent most of their time in other departments where benzene was not present. For these and other reasons, the UNC researchers certainly did not regard their study as demonstrating that low levels of benzene exposure pose no significant health risks. To the contrary, the study recommended that "[e]xposures to benzene should be maintained as far below the Threshold Limit Value [i.e., 10 ppm] as is possible." *Id.* at 35.

[3] See also the responses of Dr. Lamm and Dr. Tabershaw, testifying for respondent Manufacturing Chemists Association, to the questioning of Dr. Lloyd. Tr. 2661-2664.

Dr. Thorpe had almost no idea what proportion of the workers studied actually had been exposed to benzene, let alone how long they had been exposed (Tr. 2021-2022, 2025-2029). As was conceded by Dr. Steven Lamm, a witness for respondent Manufacturing Chemists Association ("MCA"), "there may well have been, within Dr. Thorpe's group, some subgroups which had exceedingly high rates of leukemia that he didn't identify in his analysis." Tr. 2664.[4]

An epidemiologic study which, like Dr. Thorpe's, is "diluted" by the inclusion of large numbers of unexposed workers can easily mask severe cancer risks. This is illustrated by a series of studies concerning carcinogenic coke oven emissions which demonstrate dramatically the danger of relying on a "diluted" study. The original coke oven studies were not limited to the employees who were actually exposed to the emissions from the ovens and at first did not show a significant excess incidence of cancer among the employees studied. But when the researchers went on to focus on a particular subgroup, top-side coke oven workers, who were so exposed, an enormous increase in the incidence

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[4] Industry quotes the statement of Dr. Robert Snyder, a witness for respondent American Iron and Steel Institute, that "using the most powerful statistical tools available and concentrating on the most highly exposed population of workers, it was not possible to detect a greater incidence of leukemia [in the Thorpe study] than in the population at large." API Br. at 15-16, n. 35, quoting Ex. 156-2 at 17. Industry implies that Dr. Snyder meant to indicate that the overall results of the Thorpe Study are such as to rule out the possibility that the workers included in the study who were actually exposed to benzene may have suffered a significant excess incidence of leukemia. But to the extent Dr. Snyder's statement could be so interpreted, he retracted it on cross-examination. When questioned regarding his statement, Dr. Snyder explained that in referring to "the most highly exposed population of workers," he was not referring to the particular subgroup of workers in the Thorpe study who were actually exposed to benzene; rather, he explained, "[p]eople who are working . . . in the petroleum industry [a]re exposed to a variety of chemicals and that is all it means." Tr. 3227-3228. Dr. Snyder further testified as follows:

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of lung cancer was detected.[5] As was noted repeatedly during the benzene hearing, the coke oven emissions data present a classic example of how easily a severe risk to an exposed subgroup can be obscured by data concerning a group containing large numbers of unexposed workers. See, e.g., Tr. 1437-1438, 2329.[6]

In short, as the Secretary stated, "[t]he fundamental premise of any epidemiological investigation of the potential relationship of occupational exposure to an agent and observed health effects is . . . a careful definition of an exposed cohort." Pet. App. 124a. See also Pet. App. 182a.

Dr. Lloyd: But I wonder what your point is about the use of "powerful statistical tools," what that might add to the analysis.

Dr. Snyder: His data was incomplete, but within the framework of the data that he had here, trying to draw some conclusions based on the statistics he could apply, given that these are imperfect, and given the fact that we know he didn't have complete data, he tried to do the best he could with what he had, and that was the only point that I was trying to make here. Tr. 3292-3294.

Similarly, the statement in a paper by the National Academy of Sciences that the Thorpe study "seem[s] to indicate that there is not an outstandingly high incidence of leukemia in the workers studied" (Ex. 2-4 at ii, cited in API Br. at 16, n. 36) obviously refers to the entire group studied by Dr. Thorpe, not to the subgroup of workers who were actually exposed to benzene.

[5] See Ex. 113; Ex. 217.27.D. Largely as a result of these later studies, employee exposure to coke oven emissions is now regulated by an OSHA standard, which has been upheld in pertinent part by the Court of Appeals for the Third Circuit, *American Iron and Steel Institute* v. *OSHA*, 577 F.2d 825 (1978), *petitions for cert. pending*, Nos. 78-918, 78-919.

[6] Indeed, the concessions made by industry witnesses such as Dr. Lamm and Dr. Snyder regarding the "dilution" inherent in the Thorpe study came in response to the questions of Dr. William Lloyd, who was the principal author of the coke oven studies. See, e.g., Tr. 2664.

The Thorpe study, as the Secretary found, failed to comply with this threshold requirement. See Pet. App. 110a-111a.

Nor was the "dilution" problem the only defect in the Thorpe study. The Secretary cited several others. Pet. App. 110a. For example, Dr. Thorpe's method of determining the number of leukemia deaths suffered by the workers was highly inaccurate (Tr. 2015-2029, 2071, 2074-2075). Moreover, the study excluded altogether the workers who had terminated their employment early, and the medical history of retirees was not investigated with any accuracy. (Tr. 2023-2025). Workers who terminate their employment early, and also retirees, are known to exhibit a particularly high incidence of disease, and therefore any study which excludes those groups may severely understate the cancer risk which is actually present. In this regard the classic example is a series of British studies concerning vinyl chloride, in which the very great cancer hazard posed by that substance [7] was not evident until workers who had terminated their employment early were included in the studies. See Tr. 1200, 1438-1440. As Dr. Infante testified, by excluding such workers the Thorpe study is guilty of the very flaw which was highlighted by the British vinyl chloride studies. Tr. 1200.

In short, while Dr. Thorpe may not be "ashamed" of his study (Tr. 2021), the Secretary was right in regarding the study as casting no light on the question of the leukemia risk posed by low levels of exposure to benzene.

b) *The Tabershaw/Cooper Study.* The Tabershaw/Cooper Study, relied upon by industry (API Br. at 15) suffered from the same basic flaws as the Thorpe study, but to an even greater degree. As the Secretary emphasized, this study, involving 17 selected refineries, was designed to investigate the effects of exposure to hydrocarbons in general, not benzene. Pet. App. 108a. Dr. William Gaffey,

[7] Employee exposure to vinyl chloride is regulated by an OSHA standard which was upheld in *Society of the Plastics Industry, Inc.* v. *OSHA*, 509 F.2d 1301 (2d Cir.), *cert. denied*, 421 U.S. 992 (1975).

one of the authors of the report, testified that for all he knew, fewer than 10 percent of the workers studied may have been exposed to benzene. Tr. 1411; see also Tr. 1351, 1358, 1434. The Secretary properly concluded that "since no group of workers exposed to benzene was clearly identified, this study provides no relevant information as to the leukemogenic risk of exposure to benzene." Pet. App. 108a. Dr. Gaffey in effect admitted the correctness of the Secretary's conclusion when he was asked a question comparing his study to the "diluted" coke oven studies discussed above:

> Mr. Wagoner: What I would like to ask you is given the similarities between the two studies, could you possibly have within your study population, a smaller subsegment who had been exposed to benzene who are experiencing a risk factor of the order of magnitude similar to that found by Dr. Lloyd in the steel industry, and yet by studying it in the method that you have, you would have obscured or overlooked this risk?
> Dr. Gaffey: I cannot rule out that possibility. (Tr. 1438).

In addition, just as the Thorpe study had excluded workers who terminated their employment early, so did the Tabershaw/Cooper Study. As just noted, this method of proceeding obscures the leukemia risk posed by benzene to the workers studied by Dr. Gaffey and his associates. See Tr. 1438-1440. For these reasons, the Secretary's refusal to rely on the Tabershaw/Cooper study (Pet. App. 107a-108a) was well-founded.

c) *The Stallones Study.* The study by Dr. Reuel Stallones of Shell Oil Company workers (see API Br. at 15, referring to Ex. 115.C-2) rests on no better footing. As the Secretary noted "[a]gain, failure to correctly identify or define a benzene-exposed cohort limits the usefulness of this study." Pet. App. 111a. The study included *all* Shell employees, including office workers (see Tr. 2324-2325), and Dr. Stallones had to concede that "perhaps quite a large proportion [of the group studied] are not exposed to benzene."

Tr. 2302. Nor did Dr. Stallones have any idea as to the lengths of exposures involved. Tr. 2300. Moreover, 80% of the exposures monitored were below 1 ppm. Tr. 2296. Like the other "negative studies," the Stallones study excluded workers who left their employment early. Tr. 2298. Consequently, as was made clear by Dr. Stallones' responses to questions posed by Dr. Infante, no conclusions can be drawn from this study. See Tr. 2326-2331.

d) *The Steel Industry Studies.* It is remarkable that industry should claim to find significance in "a long-term mortality study of the steel industry," which, according to industry, "showed that coke oven and by-products facilities workers, exposed over the years to low concentrations of benzene, had not experienced any excess incidence of leukemia." API Br. at 15. For these are the very coke oven studies which demonstrate the error of drawing any conclusions regarding the risk posed by a chemical from a study which does not focus specifically on workers who are actually exposed to the chemical. (See pp. 5b-6b, *supra.*)

The coke oven studies, designed to determine the incidence of cancer (particularly lung cancer) resulting from coke oven emissions, did not seek to identify a group of workers exposed to benzene. Consequently, as Dr. Lloyd, the principal author of the studies, established by his questioning of the witnesses for the American Iron and Steel Institute, there is no way to tell from the coke oven studies what the incidence of leukemia may be among those steelworkers who are actually exposed to benzene. See Tr. 3315. And see generally Tr. 3300-3306, 3313-3315. In addition, the number of employees in the work area suggested by industry as most likely to include some benzene-exposed workers—the coke plant by-products area—was too small to permit any conclusions regarding the relationship between benzene and leukemia to be drawn in any event. See Tr. 3314. In short, as is apparent from Dr. Lloyd's examination of the AISI witnesses, industry's assertion that his studies demonstrate anything with respect to benzene is a gross misuse of the studies. The Secretary properly con-

cluded that "[g]iven the small numbers of observed and expected rates of leukemia, and in the absence of a study designed to assess coke oven worker exposure to benzene . . . it [is] inappropriate to rely on these studies. . . ." Pet. App. 111a.

Summary

As this review has shown, industry's contention that low levels of exposure to benzene involve risks which are non-existent or *de minimis* finds no support whatsoever in the epidemiologic studies upon which industry relies, and was properly rejected by the Secretary.

ADDENDUM C

An Additional Analysis of the Evidence Supporting the Secretary's Finding That It is Impossible to Derive a Meaningful Risk Assessment for Benzene, and in Particular, His Rejection of Dr. Wilson's Attempted Risk Assessment.

As shown in the reply brief, *supra* at 10-14, the Secretary found that there is no way to extrapolate from the risks attributable to high concentrations of benzene to predicted risks of benzene exposure at levels of 10 ppm and below; and the court of appeals did not upset that finding. The Secretary based his finding on inadequacies in the known data and in the hypothesized theories of extrapolation. Further, the Secretary specifically considered and rejected the handwritten extrapolation prepared by Dr. Richard Wilson, a physicist, which industry submitted in the rule-making proceedings, and which, notwithstanding the Secretary's rejection, industry presents to this Court.

We show herein that an examination of the Wilson testimony illustrates the correctness of the Secretary's finding that such extrapolations regarding the risks of exposure to benzene are invalid. As we show, Dr. Wilson's method was to ignore the gaps in the existing data or, where he acknowledged that such a gap existed, to fill it in with assumptions which were designed to understate the magnitude of the projected risk.

I.

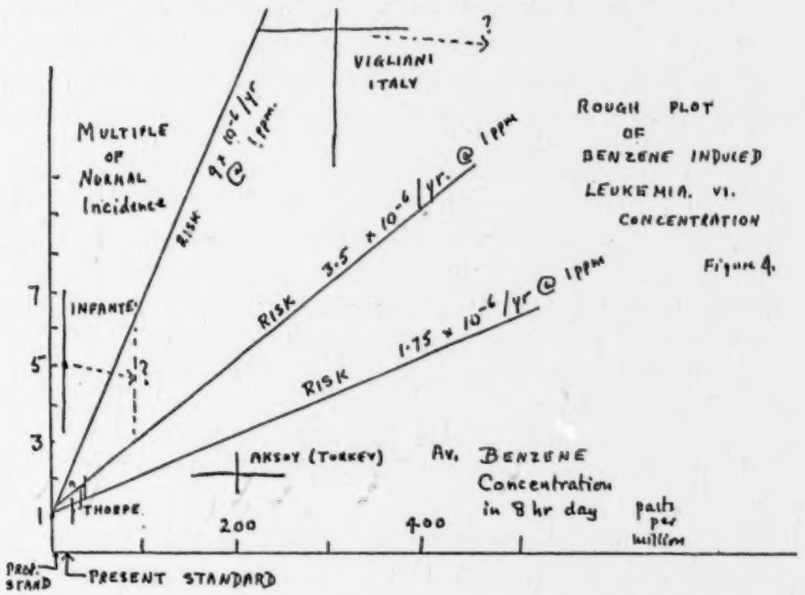
To construct an extrapolation from known points to unknown points, there must first be known points—certain dose-response points for benzene-leukemia must be identified as a predicate to any extrapolation of the response at other doses. A given "dose" of benzene is essentially a function of two factors: the *level* of benzene exposure and the *duration* of benzene exposure. Regular exposure to 1 ppm of benzene over 40 years is not the same dose of benzene as exposure to 1 ppm of benzene over a five year

period. The "response" to a given dose of benzene is the incidence of leukemia associated with that dose.

To select a starting point for his extrapolation, Dr. Wilson referred to four of the epidemiologic studies in the record: those of Drs. Infante, Vigliani, Aksoy and Thorpe. On a hand-written graph, reproduced in the margin,[1] Dr. Wilson recorded his understanding of the results of the four studies. As the graph shows, for each study Dr. Wilson recorded the exposure level he believed to have been involved, and the multiple of the leukemia incidence in the general population (i.e., the "risk factor") he believed to have been reported.[2]

But what Dr. Wilson recorded does not correspond to the

[1] Dr. Wilson's graph, which appears at App. 170, is as follows:



[2] On the graph, the horizontal axis plots benzene exposure levels and the vertical axis plots the risk factor. Each of the four studies is represented by a point on the graph, identified by the names of the four researchers. Vertical and horizontal lines extending out from each of the four points represent the range of uncertainty which Dr. Wilson believed to exist with respect to the risk factor and exposure levels involved in each study.

actual data produced by the studies. The data in fact, as the Secretary found, do not provide sufficient information to plot a dose-response curve. Dr. Wilson filled in the gaps in the data with assumptions which are not only unfounded but tend to greatly understate the risk of leukemia resulting from benzene exposure. We illustrate these points below by reference to Dr. Wilson's treatment of each of the factors involved in a dose-response analysis.

DOSE

A. *Duration.* Dr. Wilson did not even discuss the question of the duration of the benzene exposures involved in the four studies. In utilizing the studies for his extrapolation, he apparently assumed, erroneously, that the leukemia incidence reported in each study represents the risk resulting from benzene exposure spanning an *entire working life* at the levels involved in the study. See App. 89. In actuality, however, the duration of the exposures involved in each of the studies is highly uncertain, and may well have been quite short.

For example, the group of employees studied by Dr. Infante included every white male employee who worked *at any time* during the years 1940 to 1949 on a job which was thought to entail exposure to benzene at the plants in question. Ex. 40 at 5. It is impossible to estimate what the actual durations of exposure may have been. A later study involving the same plants suggests that workers may have moved frequently from jobs involving benzene exposure to jobs involving no exposure, and vice-versa. See Ex. 187.B-13 at 25. Hence the aggregate exposures reflected in the Infante study may have been short. Similarly, in both the Vigliani and Aksoy studies it is likely that the duration of exposure varied greatly from employee to employee, with many employees exposed for only a few years, and few if any employees exposed for more than fifteen or twenty years. See Pet. App. 100a-101a.[3]

[3] As for the Thorpe study, the Secretary properly found that study to be meaningless (see Addendum B, pp. 4b-5b), and we therefore do not consider it here.

A § 6(b)(5) standard must be geared to protecting an employee who "has regular exposure to the hazard dealt with by such standard for the period of his working life." To provide the information necessary under § 6(b)(5), an extrapolation must show the risk of leukemia associated with a given level of exposure over the course of an employee's entire working life: some thirty-five to fifty years. The data here do not allow for any such extrapolation. Dr. Wilson simply willed away that problem by falsely assuming that the epidemiologic studies represent the effects of lifetime exposures. His "risk assessment" is therefore not only meaningless but necessarily understated to a significant, albeit unknowable degree.

B. *Level.* In constructing his graph, Dr. Wilson had to determine the levels of exposure which had produced the leukemia incidence reported in each study. But as the Secretary found, enormous uncertainty surrounds that question. See, e.g., Pet. App. 182a. For example, in the case of the Infante study the evidence indicates that at some times the benzene concentrations at the plants in question may have been as low as 0 to 15 ppm, while at other times they may have been much higher. And with respect to that study the Secretary found:

> . . . [A]ny conclusion regarding the actual individual time-weighted average exposure is speculative. Because of the lack of definitive exposure data, OSHA cannot derive any conclusions linking the excess leukemia risk observed with any specific exposure level.

Id. at 105a.

Consequently, as Dr. Douglas Smith of NIOSH testified, it is impossible to determine what level of exposures actually caused the observed leukemia deaths reported by Dr. Infante:

> A lot of emphasis has been placed upon the fact that individuals could have been exposed to these very high levels that were basically extremes and as has been stated, it is possible but we don't know any more than

> to speculate. By the same token, one can speculate also that they were exposed to the low ranges as well, and that effects could have occurred from the low ranges.

Tr. 996.

Dr. Bernard Goldstein of the New York University Medical Center made the same point with respect to all the epidemiologic studies of benzene exposure: "[W]e really have no information as to the exposure level of any of the individuals who have developed acute leukemia." Ex. 75 at 2.

Nevertheless Dr. Wilson's graph interprets each of the epidemiologic studies as showing a particular incidence of leukemia resulting from a particular exposure level (or in some cases, a narrow range of exposure levels). Thus, in this respect as well, the Wilson risk assessment rests on an assumption contrary to fact and to the Secretary's findings.

RESPONSE

Dr. Wilson did not take into account the possibility that the studies may have greatly underreported the actual incidence of leukemia in the workers studied. Yet Dr. Infante was unable to determine whether or not twenty-five percent of the workers included in the group he studied had died, and for purposes of the study he assumed that every one of them was alive. Among the other seventy-five percent of the workers, the additional leukemia cases discovered by Dr. Sakol among the employees studied by Dr. Infante indicate that Dr. Infante's method of determining the causes of death among the workers resulted in his missing a significant number of cases of leukemia.[4] Also, many of

[4] Industry erroneously asserts, API Br. at 11, n. 19, that the additional leukemia deaths found by Dr. Sakol do not indicate that Dr. Infante's study underestimated the risk of leukemia. That assertion is contrary to the testimony of the authors of the Infante study. See Tr. 768-772, 903-905.

the workers studied were still alive, and thus their eventual cause of death cannot be known.[5]

As a result of these and other factors, Dr. Infante's own assessment was that his study had "tremendously underestimated the true risk of leukemia in this population. . . ." Tr. 768; see also Tr. 874-875. Edward Baier, then Deputy Director of NIOSH, agreed with that assessment. Tr. 747. And Dr. Sakol's conclusion was that the Infante study "grossly underestimates the incidence" of leukemia in the workers studied. Tr. 314.

Similarly, by Dr. Aksoy's own account, the Aksoy study substantially understates the actual incidence of benzene leukemia among the workers he studied (Ex. 60 at 1-2). And the Thorpe study was designed in a manner which tends so patently to understate the risk of benzene leukemia that the Secretary properly found that study to be meaningless. See Addendum B, pp

Nevertheless, in performing his risk assessment Dr. Wilson did not take into account the likelihood that all of the epidemiologic studies may seriously underestimate the risk of benzene leukemia. To the contrary, as we next discuss, he arbitrarily chose to assume that the Infante and Vigliani studies had greatly *overstated* the risk.[6]

For the reasons just stated, Dr. Wilson's "risk assessment," based on the studies of Drs. Infante, Vigliani, Aksoy and Thorpe, would contain fatal deficiencies even if the four studies were consistent in their results. But in fact the results of the four studies are not consistent, and Dr. Wilson therefore found it necessary "to make sense out of this highly discorded [sic] set of data." App. 88. In order to "make sense" out of the data, Dr. Wilson chose to assume that the Infante data had *overstated* the risk to the population Dr. Infante had studied,[7] while in reality, as we have shown, the Infante data were almost certainly *understated*. Dr. Wilson also assumed that the studies of Dr. Vigliani were overstated.[8] As a physicist who lacked any special ability to determine the validity of any of the epidemiologic studies in the record, Dr. Wilson did not reach his assessment of the Infante and Vigliani data on the basis of any expert evaluation of that data. Rather, he believed that the results reported by Drs. Infante and Vigliani should be discounted merely because they appeared to be inconsistent with the studies of Dr. Aksoy and Dr. Thorpe—this despite the fact that the Aksoy data, even according to Dr. Aksoy, underestimate the risk, and that the Thorpe study contains such manifest flaws that the Secretary properly rejected its findings. See p. 3c, n. 3, *supra*.

Dr. Wilson's arbitrary and erroneous decision to discount the results of the Infante and Vigliani studies led him to base his calculations on an assumed dose-response curve, which he described as "slightly better than a guess" (App. 92), and which predicts a risk much smaller than the risk which he would have predicted had he not regarded the Infante and Vigliani data as overstated.[9]

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[5] The foregoing facts appear at Pet. App. 102a-103a, 104a-105a, 107a. See also the material cited in our opening brief at 9-10, n. 4.

[6] An additional flaw in Dr. Wilson's response "calculation" is the following: in utilizing the four studies Dr. Wilson made no allowance whatsoever for the critical fact that susceptibility to benzene leukemia varies among different individuals and groups. See the reply brief, *supra* at p. 12, n. 15. Dr. Wilson thus simply disregarded a consideration which introduces uncertainties of unknown dimensions into any attempted risk assessment for benezene.

What is more, while Dr. Wilson made the peculiar assumption that for each case of benzene leukemia there will be an additional case of some other form of cancer, and he therefore multiplied his dose-response projections by a factor of two (App. 171), he did not take into account any of the known benzene-related risks other than cancer, such as aplastic anemia. Any attempt to factor in these additional risks would involve the same problems as are presented with respect to assessing the leukemia risk. See, e.g., Pet. App. 82a-98a, 160a.

[7] See App. 171, 88, 92-93.

[8] *id.* at 88.

[9] The extent to which Dr. Wilson discounted the Infante and Vigliani data can be seen by examining Dr. Wilson's graph (see note 1, *supra*).

II.

The Secretary found that apart from inadequacies in the data, there is no satisfactory theory of extrapolation from known carcinogenic effects of a substance at high exposure levels to projected carcinogenic effects of the substance at lower exposure levels. Dr. Wilson chose to estimate the risks of benzene exposure at low levels by drawing a *linear* dose-response curve, *viz.* he assumed that the risks are directly proportional to the level of exposure. See note *supra*. But Dr. Wilson conceded that the actual dose-response curve could well be very different from the linear extrapolation he employed (Tr. 2719-2720), and that "any dose-response curve is possible." App. 93.

Dr. Wilson described the linear extrapolation technique as a "fairly prudent and slightly conservative" assumption (App. 89). But Dr. Lloyd suggested that at high levels of benzene exposure, the number of diagnosed leukemias may be reduced by the fact that many workers may die of other benzene-induced diseases such as aplastic anemia before the onset of leukemia, while at low levels this phenomenon

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In constructing dose-response curves on his graph, Dr. Wilson assumed that such curves would be linear, i.e., that risk is directly proportional to exposure. Consequently, the dose-response curve attributable to any given study under Dr. Wilson's system would consist of a line between the point which represents the results of that study and the point on the vertical axis of the graph which represents a normal incidence of leukemia (i.e., a risk factor of one) at zero exposure. (On the graph, the latter point is where the three lines marked "risk" intersect).

The dose-response curve which Dr. Wilson selected to predict the risk of benzene leukemia is the line marked "1.75 x 10^{-6}/yr. @ 1 ppm" on the graph (App. 171). On that dose-response curve, a risk factor of 7 would occur at approximately 550 ppm. Yet on his graph, Dr. Wilson recorded the Infante data as showing a risk factor as high as 7 at exposures somewhere between *10 ppm and 100 ppm*. Similarly, Dr. Wilson plotted the Vigliani data as showing a risk factor of approximately 15 at exposures of approximately 300 ppm (and the risk factor actually reported by Dr. Vigliani was 20, see Pet. App. 100a); yet the dose-response curve selected by Dr. Wilson shows a risk factor of only *4* at that level of exposure.

may not be present to the same degree. If that were the case, a linear extrapolation would understate the leukemia risk at low levels of exposure, and a curve rising steeply at low doses and flattening out at the top would be accurate. Dr. Lloyd stated, based on his experience, that similar circumstances have been found to exist with respect to beryllium and asbestos, and he asked Dr. Wilson whether the same might not be true of benzene, "[p]articularly in light of Dr. Aksoy's report with so many of the shoemakers dying from their blood dyscrasia [a non-malignant disorder]." App. 93. Dr. Wilson replied that he could not rule out that possibility. *Ibid.*

The possibility discussed by Dr. Lloyd is only one of many factors which indicate that the "linear hypothesis" may lead to an underestimate of the risk of low-level benzene exposures. As a commentator has observed, "[u]ntil we have a detailed understanding of the molecular mechanisms of carcinogenesis, we have no basis for saying whether the 'linear hypothesis' assures an adequate margin of safety." Lovins, *Cost-Risk-Benefit Assessments in Energy Policy*, 45 Geo. Wash. L. Rev. 911, 922 (1977).

III.

Finally, even if a meaningful dose-response curve could be constructed, an additional problem would remain. The actual number of deaths which the standard would prevent cannot be determined in the absence of information as to the number of workers who, were the permissible exposure level not reduced below 10 ppm, would be exposed at each level between 10 ppm and 1 ppm. The data on this point are very imprecise, and Dr. Wilson admitted that his calculations were based on an assumption that without the standard now under review, workers would be exposed to 3 ppm of benzene. This assumption surely understates the extent to which the standard would reduce exposures, and therefore leads to an underestimate of the health benefits which would result from the standard. As Dr. Wilson conceded (App. 90):

"I tried to [determine] . . . who is exposed to what. . . ., but I didn't find it. * * * * So I made a very rough guess that they were three parts per million.

Dr. Wilson further conceded that this "guess" was based on at least one inaccurate assumption (*Ibid.*):

MS. KALARIS: I believe you stated that only a few 100 people would be regularly exposed to 10 ppm of benzene concentration. Can you explain the basis of that statement?

DR. WILSON: That is maybe incorrect. It came out of a page in this report here, and again, they were vague on this particular question. Therefore, I am a little vague on it. Probably, as I was thinking about it last night, I think a few hundreds; it is probably closer to 1,000 than 100, but I really don't know."

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1978

INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*,
Respondents;

RAY MARSHALL, SECRETARY OF LABOR,
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

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BRIEF FOR NATURAL RESOURCES DEFENSE COUNCIL, INC. AS *AMICUS CURIAE*

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1978

No. 78-911

INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*,
Respondents;

No. 78-1036

RAY MARSHALL, SECRETARY OF LABOR
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

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BRIEF FOR NATURAL RESOURCES DEFENSE COUNCIL, INC. AS *AMICUS CURIAE*

INTEREST OF *AMICUS CURIAE* NATURAL RESOURCES DEFENSE COUNCIL

The Natural Resources Defense Council, Inc. ("NRDC")—a national environmental organization with more than 44,000 members residing in all states and territories, as well as abroad—has as one of its principle objectives the prevention of environmentally-caused disease. The prevention of cancer caused by exposure to man-made chemicals is among the highest of NRDC's priorities, in view of the fact that it is responsibly estimated that the majority of the cases of this dreaded disease are caused by such chemicals.

In pursuit of this objective, NRDC closely monitors the development of federal cancer policies in the Department of Labor, the Environmental Protection Agency, and other federal agencies that are responsible for protecting the public from exposure to cancer-causing substances in the workplace and general environment. Recently, for example, NRDC submitted detailed scientific and policy comments on the proposed general cancer policy of the Department of Labor. NRDC has also played a similar role in the development of the general cancer policies of the Environmental Protection Agency and the Food and Drug Administration.

NRDC has also played an important part in a number of administrative proceedings relating to specific toxic substances with carcinogenic properties. NRDC was among the first to call to the government's attention the scientific evidence that synthetic fluorocarbons damage the stratospheric ozone layer, which protects the world's people from solar radiation that causes skin cancer. This evidence later become the basis for executive and legislative actions to limit nonessential uses of fluorocarbons. NRDC also brought to the attention of the Food and Drug Administration the potential cancer-causing properties of

certain kinds of plastic soft drink bottles, which that agency has since decided should not be used.

In the Occupational Safety and Health Act, and a number of other major laws, the Congress of the United States has responded to the growing national concern over the rapid increase in, and grim results of, exposure to cancer-causing substances. NRDC and its members have a substantial interest in preserving the integrity of these laws, in view of the importance of environmental factors in causing cancer. In addition, NRDC and its members have an interest in the outcome of this case because the basic legal issues presented here permeate the entire body of the Congressional enactments to control the incidence of cancer. This Court will provide an authoritative interpretation of the Occupational Safety and Health Act, which will affect as well the many other federal laws designed to reduce the toll from cancer.

Regarding the issues presented here, NRDC believes the Secretary properly interpreted the Occupational Safety and Health Act when he concluded that it committed to his discretion the question whether quantifying the magnitude of the risk of cancer-causing substances, and balancing the costs and benefits of proposed regulations, could be done with sufficient precision to provide useful guidance in establishing the preventive standards required by the Act. In addition, we believe the Secretary properly exercised this discretion when he concluded that these techniques were too immature to inform his judgment meaningfully. As discussed in this brief, we agree with the Secretary that quantitative risk assessment, and cost-benefit analysis, are now too primitive to be thrust into the prominent role envisioned by the court below. If the objectives of the law are to be achieved, it is essential that this Court uphold the Secretary's authority to act to prevent cancer on the basis of the best available evidence, rather than forcing the public to wait for the development

of a degree of precision that is, at least at present, beyond the capabilities of science.

All parties to both cases consented to the filing of a brief by NRDC as *amicus curiae*. Copies of the letters of consent are filed with this brief.

QUESTIONS PRESENTED

1. Whether the Occupational Safety and Health Act provides authority for the Secretary of Labor to limit employees' exposure to carcinogenic chemicals to the extent feasible on the basis of qualitative evidence that they cause cancer, rather than requiring him to withhold regulation until he has information sufficiently detailed to permit quantitative assessment of the magnitude of the health risk, and until he performs a quantitative cost-benefit analysis of contemplated standards.

2. Whether the Secretary acted within his discretion when he determined that the techniques of quantitative risk assessment and cost-benefit analysis would not usefully sharpen his judgment in establishing a standard to prevent cancer induced by workplace exposure to benzene.

INTRODUCTION AND STATEMENT OF THE CASE

A. The Problem of Occupational Disease.

In 1970, Congress determined that the devastating toll of deaths, illnesses and injuries caused in American workplaces must be drastically reduced. Occupational accidents alone then claimed more than 14,500 lives and disabled at least 2.2 million people each year.[1] Each year chemicals and dusts in the workplace caused at least

[1] S. REP. NO. 1282, 91st Cong., 2 Sess. 2 (1970) [hereinafter cited as SENATE REPORT].

390,000 new cases of occupational illness.[2] Congress concluded that the engine of American prosperity had to be made safer for those who operated it. To this end Congress enacted the Occupational Safety and Health Act,[3] whose primary purpose is "to assure so far as possible every working man and woman in the Nation safe and healthful employment and places of employment."[4]

The legislators set special emphasis on controlling the careless use of toxic substances in the workplace, which are causing cancer, respiratory and heart diseases, nervous disorders, sterility and other killing and disabling diseases. The Senate and House Committees cited chemical dangers running the gamut from the "ancient" poisons such as lead and mercury to the newest exotic products of the Petrochemical Age:

> [M]aterials long in industrial use are only now being discovered to have toxic effects. In addition, technological advances and new processes in American industry have brought numerous new hazards to the workplace. Carcinogenic chemicals, lasers, ultrasonic energy, beryllium metal, epoxy resins, pesticides, among others, all present incipient threats to the health of workers. Indeed, new materials and processes are being introduced into industry at a much faster rate than the present meager resources of occupational health can keep up with. It is estimated that every 20 minutes a new and

[2] *Id.* at 3. The Committee stated: "In the field of occupational health, the view is particularly bleak, and, due to the lack of information and records, may well be considerably worse than we know." *Id.* at 2.

[3] PUB. L. NO. 91-596, 84 Stat. 1591 (codified at 29 U.S.C. §§ 651-678).

[4] *Id.* §2(b), 29 U.S.C. §651(b).

> potentially toxic chemical is introduced into industry. New processes and new sources of energy present occupational health problems of unprecedented complexity.[5]

Congress took especially seriously the developing edge of scientific knowledge showing alarming trends in occupationally induced disease:

> Recent scientific knowledge points to hitherto unsuspected cause-and-effect relationships between occupational exposures and many of the so-called chronic diseases—cancer, respiratory ailments, allergies, heart disease, and others. In some instances, the relationship appears to be direct: asbestos, ionizing radiation, chromates, and certain dye intermediaries, among others, are directly involved in the genesis of cancer. In other cases, occupational exposures are implicated as contributory factors. The distinction between occupational and non-occupational illnesses is growing increasingly difficult to define.[6]

Since 1970, these findings and predictions have been amply borne out.

The chemical hazard most on the public's and Congress' mind, then and now, is cancer. One American in four will contract some form of cancer; one in five is expected to die from it.[7] The concensus of scientific experts is that the majority of cancer is caused by exposure to

[5] SENATE REPORT, *supra* note 1, at 2.

[6] *Id.*

[7] COUNCIL ON ENVIRONMENTAL QUALITY, SIXTH ANNUAL REPORT 12 (1975); Cairns, *The Cancer Problem*, SCIENTIFIC AMERICAN November 1975, at 66.

chemical substances.[8] At least a fifth—perhaps a third or more—of all cancer in the United States is related to chemicals in the workplace.[9] A grim list of specific occupational chemicals has been identified as carcinogenic and continues to grow.[10] Benzene, which causes leukemia, is one such substance.

B. The Occupational Safety and Health Act

The Occupational Safety and Health Act authorizes the Secretary of Labor to set standards to protect employees from toxic substances. The Act provides for three kinds of standards for such substances. As an interim measure, section 6 (a) of the Act directed the Secretary by 1972 to promulgate as federally enforceable standards any existing "national consensus standards."[11] These are safety and health standards developed before 1970, generally by industry-funded organizations, and voluntarily agreed to by individual companies.[12] In 1971 the Secretary

[8] World Health Organization, Prevention of Cancer, Technical Report No. 276 (1974); Higginson, *Importance of Environmental Factors in Cancer in* ENVIRONMENTAL POLLUTION AND CARCINOGENIC RISKS 15, 17 (C. Rosenfield & W. Davis, eds. 1975); Boyland, *The Correlation of Experimental Carcinogenesis and Cancer in Man*, 11 PROGRESS IN EXPERIMENTAL TUMOR RESEARCH 222, 223 (1969); Epstein, *Environmental Determinants of Human Cancer*, 34 CANCER RESEARCH 2425 (1974). *See also* R. DOLL, PREVENTION OF CANCER: POINTERS FROM EPIDEMIOLOGY (1967).

[9] Bridbord, Decoufle, Fraumeni, Hoel, Hoover, Rall, Saffiotti, Schneiderman & Upton, *Estimates of the Fraction of Cancer in the United States Related to Occupational Factors* (U.S. HEW 1978).

[10] *See* Cole & Goldman, *Occupation*, in PERSONS AT HIGH RISK OF CANCER, AN APPROACH TO ETIOLOGY AND CONTROL 167 (1975). [hereinafter cited as PERSONS AT HIGH RISK OF CANCER].

[11] 29 U.S.C. §655(a).

[12] SENATE REPORT, *supra* note 1, at 5-6.

adopted some 400 such standards for air contaminants, including the existing 10 parts per million (ppm) standard for benzene.[13] These standards merely codified contemporary industry self-regulation. Generally they were set at levels necessary to prevent only the acute and chronic effects of moderately high exposures. They were not designed to protect against the long-term adverse effects of lower doses, which largely had not been investigated. This was the case for the benzene standard, which was aimed only at some of the chemical's nonmalignant effects.[14] The Senate and House Committees made clear that national consensus standards were not substitutes for more protective standards when further research demonstrated the need.[15]

Section 6(c) empowers the Secretary to set without rule-making "emergency temporary standards" when necessary to protect employees from "grave danger" due to new or newly discovered hazards.[16] These are effective immediately upon promulgation, and must be replaced by so-called "permanent" standards within six months, which must be developed through normal rulemaking procedures.[17] In May 1977, The Secretary promulgated an emergency temporary standard of one ppm for benzene upon concluding that it causes leukemia.[18]

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[13] 36 Fed. Reg. 10,466 (1971), codified in 29 C.F.R. §1910.1000 table Z-1.

[14] 43 Fed. Reg. 5919 (1978) (preamble to the Secretary's benzene standard).

[15] SENATE REPORT, *supra* note 1, at 6; H.R. REP. NO. 1291, 91st Cong., 2d Sess. 17 (1970) [hereinafter cited as HOUSE REPORT].

[16] Occ. Safety & Health Act §6(c)(1), 29 U.S.C. §655(c)(1).

[17] *Id.* §6(c)(2)-(3), 29 U.S.C. §655(c)(2)-(3).

[18] 42 Fed. Reg. 26429 (1977). The standard never became effective. It was stayed by the Fifth Circuit, American Petroleum Inst. v. OSHA, No. 77-1516 (stay ordered, May 20, 1977), and the case was rendered moot by the promulgation of the final standard and the judicial challenge here under review.

The main vehicle for protecting employees from toxic substances is the so-called "permanent standard," established under Section 6(b), the provision at issue in this litigation.[19] This Act sets out the criteria for such standards in the detailed provisions of Section 6(b)(5). The Secretary must set the standard for such a substance

> which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws.[20]

Section 6(b) provides for informal rulemaking, supplemented by an opportunity for a public hearing.[21] Section 6(e) requires the Secretary to give a statement of reasons with each standard.[22] Section 6(f) provides for pre-enforcement review of such standards in the Courts of Appeals; the court must uphold the Secretary's determinations if they are supported by substantial evidence.[23]

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[19] 29 U.S.C. §655(b).

[20] *Id.* §655(b)(5).

[21] *Id.* §655(b)(1)-(4).

[22] *Id.* §655(e).

[23] *Id.* §655(f).

C. The Benzene Standard

The Secretary promulgated a section 6(b)(5) permanent standard for benzene in February 1978, after extensive comment and hearings.[24] The standard reduced the permissible benzene exposure from 10 parts per million ("ppm") to one ppm.[25] The Secretary accompanied the standard with a detailed statement of the reasons for this reduction. He based the requirement both on benzene's clearly demonstrated leukemogenicity and on its capacity to cause a wide variety of non-malignant disorders of the blood-forming system. The most recent study was by the National Institute for Occupational Safety and Health,[26] of employees in Ohio exposed to benzene in the manufacture of Pliofilm.[27] The study showed at least a five-fold excess of leukemia over the unexposed population in these workers.[28] The Secretary concluded that because benzene was a carcinogen, a safe level of exposure could not be demonstrated. Finally, he concluded that the reduction to one ppm would produce "appreciable" health benefits, in terms of reduced risk of both cancer and other benzene-induced disease.[29]

Facing a life-threatening substance for which no safe level of exposure could be established, he determined that under section 6(b)(5) he must reduce benzene exposure to "the extent feasible."[30] After carefully estimating the

[24] 43 Fed. Reg. 5918 (1978), 29 C.F.R. §1910.1028.

[25] 29 C.F.R. §1910.1028(c).

[26] The Occupational Safety and Health Act established NIOSH as an institute in the National Institutes of Health, under the Department of Health, Education and Welfare, and gives it duties to perform research and to aid the Secretary in setting standards. Occ. Safety & Health Act §§20-22, 29 U.S.C. §§669-671.

[27] Infante, Wagoner, Rinsky & Young, *Leukemia in Benzene Workers*, THE LANCET, July 9, 1977, at 76.

[28] *Id.*

[29] 43 Fed. Reg. 5940 (1978).

[30] *Id.* at 5934, 5940-41.

total costs of compliance by the industries making and using benzene, the Secretary concluded that a permissible exposure level of one part per million was feasible, as, even under the industries' cost assumptions, "the economic impact of the final benzene standard will not be such as to threaten the financial welfare of the affected firms or the general economy."[31]

The Secretary rejected the claims—then raised under the rubric of "feasibility"—that prior to setting a standard to protect employees from an undisputed carcinogen, he must quantify the cancer risk reduction the standard would achieve and show through a quantitative cost-benefit analysis that the standard's health benefits outweighed its economic costs. For reasons detailed below, he concluded that techniques do not exist to quantify risks with accuracy and reliability necessary to be of use to him in making his decision.[32] Moreover, he concluded that no basis exists to determine the value of life and health in dollars, so that no objective method of conducting a quantitative cost-benefit analysis existed. Neither form of quantitative analysis would "significantly clarify the ultimate decision."[33]

The Secretary observed that the Occupational Safety and Health Act does not require him to delay regulation of known cancer-causing substances until precise quantitative knowledge of the number of cancers that will occur at particular doses can be established.

Rather, he stated that he must act now to protect the employees from known causes of killing and disabling illness. As the House Report stated, he must act on the basis of the best available evidence and must not be "paralyzed by debate surrounding diverse medical opinions."[34] When facing a life-threatening substance for

[31] *Id.* at 5939.

[32] *Id.* at 5940-41.

[33] *Id.*

[34] HOUSE REPORT, *supra* note 15, at 18.

which no safe dose can be determined, the Secretary determined that the Act directs him to reduce employee exposure to the extent feasible. Citing prior cases,[35] he concluded that a standard which closed whole industries or forced a substantial fraction of employers in an industry out of business would not be feasible. But short of this drastic result, he concluded employees are entitled by the Act to protection from such hazards.[36]

D. The Lower Court Decision

The American Petroleum Institute and other trade organizations and individual companies sought review of the standard in the United States Court of Appeals for the Fifth Circuit. The court vacated the standard in October 1978.[37]

The lower court decision held, for the first time, that in setting a standard under section 6(b)(5) for an undisputed carcinogen, the Secretary must quantify the health benefits the standard would provide and show through a quantitative cost-benefit analysis that the benefits bear a "reasonable relationship" to the costs. The court based this holding not on the requirement that achieving the standard be "feasible" as required by Section 6(b)(5), but on Section 3(8), which defines an occupational safety and health standard as a standard "which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment."[38] As additional bases for the court's conclusion that the Secretary must have quantitative knowledge of the size of cancer risks at particular doses before he may set a standard, the court pointed to four phrases in Section 6(b)(5)—"the best available evidence," "research, demonstrations, experiments, and such other information as may be appropriate," "the latest available scientific data in the field," and "experience gained under this and other health and safety laws."[39]

[35] Industrial Union Dep't AFL-CIO v. Hodgson, 499 F.2d 467 (D.C. Cir. 1974); AFL-CIO v. Brennan, 530 F.2d 109 (3rd Cir. 1975).

[36] 43 Fed. Reg. 5934 (1978).

[37] American Petroleum Inst. v. OSHA, 581 F.2d 493 (5th Cir. 1978).

[38] *Id.* at 502-03; 29 U.S.C. §652(8).

Finally, although the court conceded the Secretary had acted rationally, it held the Secretary's conclusion that "appreciable" health benefits would flow from the standard not to be supported by substantial evidence. The court held that substantial evidence could be provided only by a quantitative assessment of the risks.[40]

E. Scientific and Policy Issues Related to the Reliability of Quantitative Risk Assessment and Quantitative Cost-Benefit Analysis

A correct appraisal of the requirements of the Act and the reasonableness of the Secretary's actions depends on a firm understanding of the techniques of risk assessment and quantitative benefit analysis. Weighing the costs and benefits of a proposed regulation of the sort under review requires being able to quantify the magnitude of the health and economic interests at stake, and to know the appropriate way to balance them.

1. *The Best Available Scientific Knowledge Permits Reliable Identification of Carcinogens, But Not Reliable Quantification of Risk*

The main tools for identifying chemicals that cause cancer are studies of exposed human populations (epide-

[39] 581 F.2d at 504; Occ. Safety & Health Act §6(b)(5), 29 U.S.C. §655(b)(5).

[40] 581 F.2d at 503.

miology)[41] and laboratory studies on animals.[42] These techniques provide a well-recognized basis for identifying chemicals posing carcinogenic risk for humans. The validity of these techniques has been confirmed repeatedly for two decades by expert scientists and scientific institutions.[43] They have been accepted by Congress,[44] the

[41] Hoover, *Detection of Environmental Cancer Hazards: Epidemiological Methods*, 75 J. OF THE MEDICAL SOC. OF N.J. 746 (1978) [hereinafter cited as Hoover]; Hoover, *Cancer Epidemiology*, in ENVIRONMENTAL CANCER: CAUSES, VICTIMS, SOLUTIONS 4 (1978) [hereinafter cited as ENVIRONMENTAL CANCER]; Mancuso, *Comments for Opening of Discussion of "Neoplastic Effects,"* 246 ANNALS OF THE N.Y. ACADEMY OF SCIENCES 251 (1975) [hereinafter cited as Mancuso]. *See generally* articles in PERSONS AT HIGH RISK OF CANCER, *supra* note 10, and in ORIGINS OF HUMAN CANCER, Book A (Hiatt, Watson, & Winsten eds. 1977) [hereinafter cited as ORIGINS OF HUMAN CANCER].

[42] CARCINOGENICITY TESTING, A REPORT OF THE PANEL ON CARCINOGENICITY OF THE CANCER RESEARCH COMM'N, INTERNATIONAL UNION AGAINST CANCER (UICC) (1969); Saffiotti, *Identifying and Defining Chemical Carcinogens*, in ORIGINS OF HUMAN CANCER, *supra* note 41, Book C, at 1311.

[43] *E.g.*, REPORT OF THE SURGEON GENERAL'S AD HOC COMMITTEE ON THE EVALUATION OF LOW LEVELS OF ENVIRONMENTAL CARCINOGENS (1970), *reprinted in Chemicals and the Future of Man, Hearings before the Subcomm. on Executive Reorganization and Government Research of the Senate Comm. on Government Operations*, 92d Cong., 1st Sess. 180 (1971). [hereinafter cited as SURGEON GENERAL'S REPORT]; NATIONAL ACADEMY OF SCIENCES, DRINKING WATER AND HEALTH 29-59 (1977) [hereinafter cited as DRINKING WATER AND HEALTH]; OFFICE OF TECHNOLOGY ASSESSMENT (U.S. CONGRESS), CANCER TESTING TECHNOLOGY AND SACCHARIN (1977); NATIONAL ACADEMY OF SCIENCES, AN EVALUATION OF THE CARCINOGENICITY OF CHLORDANE AND HEPTACHLOR (1977) [hereinafter cited as NAS CHLORDANE/HEPTACHLOR EVALUATION]; NATIONAL ACADEMY OF SCIENCES, PRINCIPLES FOR EVALUATING CHEMICALS IN THE ENVIRONMENT (1975); MINISTRY OF HEALTH & WELFARE (CANADA), THE TESTING OF CHEMICALS FOR CARCINOGENICITY, MUTAGENICITY, AND TERATOGENICITY (1975); REPORT OF THE SECRETARY'S COMMISSION ON PESTICIDES AND THEIR RELATIONSHIP TO ENVIRONMENTAL HEALTH (U.S. HEW 1969). For an early report reaching these conclusions, *see* World Health Organization, Evaluation of the Carcinogenic Hazards of Food Additives, Technical Report No. 220 (1961).

[44] *See e.g.*, Toxic Substances Control Act, §4, 15 U.S.C. §2603, which requires testing for carcinogenicity, among other effects.

agencies,[45] and the Courts of Appeals[46] as a valid basis for preventive regulation.

But at this time these techniques do not permit reliable quantification of human risk, particularly at and below levels to which employees are currently exposed. Even where a qualitative causal relationship is clearly visible, as is the case for benzene, reliable quantitative risk estimates for humans cannot be made. For a given substance the risk estimates from equally respected quantitative models—each based on different plausible assumptions about how chemicals cause cancer—differ by a factor of 5,000,000 or more.[47]

Facts such as these have led some of the nation's leading scientific experts in cancer cause and prevention to conclude that quantitative risk assessment (and thus cost-benefit balancing) are not useful aids to standard-setting at this point. Dr. Arthur C. Upton, who is Director of the nation's anti-cancer program at the National

[45] See *e.g.*, the Secretary's Proposed Carcinogen Policy, 42 Fed. Reg. 54,148 (1977), and the Environmental Protection Agency's Interim Carcinogen Policy, 41 Fed. Reg. 21,402 (1976).

[46] *See e.g.*, Environmental Defense Fund v. EPA, —F.2d—, 8 ELR 20765 (D.C. Cir. 1978) (PCBs, toxic water pollutants); American Iron & Steel Inst. v. OSHA, 577 F.2d 825 (3rd Cir. 1978) (coke oven emissions); Society of the Plastics Industry v. OSHA, 509 F.2d 1301 (2d Cir. 1975), *cert. denied* 421 U.S. 992 (1975) (vinyl chloride); Synthetic Organic Chemical Mfrs. Ass'n v. Brennan, 503 F.2d 1155 (3rd Cir. 1974) (ethyleneimine); Industrial Union Dep't AFL-CIO v. Hodgson, 499 F.2d 467 (D.C. Cir. 1974) (asbestos); Certified Color Mfrs. Ass'n v. Matthews, 543 F.2d 284 (D.C. Cir. 1976) (food color additives); Environmental Defense Fund v. EPA, 510 F.2d 1291 (D.C. Cir. 1975) (pesticides aldrin/dieldrin).

[47] NATIONAL ACADEMY OF SCIENCES, SACCHARIN: TECHNICAL ASSESSMENT OF RISKS AND BENEFITS 3-72, Table 3-8 (1978) [hereinafter cited as NAS SACCHARIN STUDY].

Cancer Institute, summarized their conclusions recently as follows:

> Based on current scientific knowledge it is not possible to accurately calculate risks for most substances. Various recently developed statistical methods attempt to extrapolate from animal data to human risk, thereby computing an estimate of how many persons in a given population can be expected to get cancer from a given dosage of a particular carcinogen. But the process has severe limitations.
>
> . . .
>
> We have the scientific means to identify substances which cause cancer in animals and which are, therefore, potential carcinogens for humans. There is as yet, however, no scientific way to arrive at quantitative and precise risk estimates for humans based on extrapolating from animal data and, therefore no scientific basis for accurately and confidently weighing the benefits of a particular substance against its risks as a potential carcinogen.[48]

The basic biochemical mechanisms of chemically-induced cancer are as complicated as life itself. They are not adequately understood, and the uncertainties will undoubtedly be removed only through years of research, depending largely on unpredictable, serendipitous insight. In the interim, however, we have the means to identify qualitatively many carcinogenic chemicals.

a. *The Basic Biochemical Processes of Cancer Causation are Largely Unknown*

The biological mechanism by which chemicals cause cancer is not well understood. There is general agreement

[48] Upton, Speech to American Cancer Society Science Writers' Seminar, Mar. 25-28, 1979, at 2-3.

that chemical carcinogenesis involves changes in the genetic material of an individual cell, or small group of cells, or in the mechanisms by which cells regulate growth and differentiation. These changes cause the affected cells to grow without restraint, without performing the functions of normal cells, and eventually threatening the life of the host.[49]

These processes appear to be enormously complex. Some chemicals appear to accomplish these changes directly. Most seem to need to be "activated" by being metabolized by the body into the actually carcinogenic substances. Still other chemicals apparently "potentiate" or otherwise facilitate the action of others. Which chemicals operate in which of these manners is not always known.[50]

In addition, cancers usually appear to be the result of a sequence of steps: a series of changes caused in the same cells by repeated exposures to the same chemical, by a sequence of exposures to different substances, or a complex interaction of chemicals with genetic susceptibility, viruses or radiation. The theory of sequential steps suggests that cancer may be caused even by past exposure to a chemical long since eliminated from the body; that chemical may have been responsible for an early step in a process completed by other factors.[51]

[49] *See* BRAUN, THE BIOLOGY OF CANCER (1974); Weinstein, Yamaguchi, Gebert, & Kaighn, *Use of Epithelial Cell Cultures for Studies on the Mechanism of Transformation by Chemical Carcinogens*, 11 IN VITRO 130 (1975).

[50] *See* Weisburger, *Chemical Carcinogens*, in TOXICOLOGY 333 (Casarett & Doull eds. 1975) [hereinafter cited as Weisburger].

[51] Crump, Hoel, Langley & Peto, *Fundamental Carcinogenic Processes and Their Implications for Low Dose Risk Assessment*, 36 CANCER RESEARCH 2973 (1976) [hereinafter cited as Crump *et al.*].

The complexity of the processes by which a chemical gets from its point of entry (*e.g.*, lungs, skin, digestive system) to its point of damage adds further uncertainty. These absorption, distribution, and excretion processes are rarely more than partly known.[52] It also appears that there are certain chemical reactions that can "detoxify" some amounts of some carcinogens and perhaps certain biological mechanisms that can repair or destroy some damaged cells. These mechanisms do not appear to be fully effective, however.[53]

Moreover, the human population is genetically, geographically, and culturally heterogeneous. For this reason, it is thought that people vary in sensitivity to a particular carcinogen. It appears that genetic heterogeneity alone accounts for a substantial variation in human response. Subgroups exposed to other substances because of their diet, or place of residence or work, may be especially sensitive to particular substances.[54]

These apparent properties of chemically-induced cancer have led to a virtual consensus among expert scientists, committees, and institutions that "thresholds" for carcinogens—*i.e.*, doses for which no human cancer risk exists—cannot be determined.[55] While theoretically a threshold dose may exist for a given person exposed to a given substance in particular conditions, the enormous variation in sensitivities and in past and future exposures

[52] GOLDSTEIN, ARONOW, & KALMAN, PRINCIPLES OF DRUG ACTION: THE BASIS OF PHARMACOLOGY 129-226 (2d ed. 1974).

[53] *See id.* at 623-667. See also Weisburger, *supra* note 50.

[54] DRINKING WATER AND HEALTH, *supra* note 43, at 39; *see generally* articles in PERSONS AT HIGH RISK OF CANCER, *supra* note 10.

[55] *See e.g.*, SURGEON GENERAL'S REPORT, *supra* note 43; Schneiderman, Decoufle & Brown, *Thresholds for Environmental Cancer: Biological and Statistical Considerations*, —ANNALS OF THE N.Y. ACADEMY OF SCIENCES— (in press); DRINKING WATER AND HEALTH, *supra* note 43, at 37-48, NAS CHLORDANE/HEPTACHLOR EVALUATION, *supra* note 43.

to this and other substances is thought to preclude determining reliable thresholds for whole populations. For the same reasons, the size of the risk at particular doses may vary greatly for different people. Even if the size of the risk for a given person in given circumstances could be demonstrated, one would not necessarily know the size of the risk for members of a larger group.[56]

b. *Epidemiological Studies Are Capable of Identifying Carcinogens, But Not the Magnitude of Cancer Risks*

Epidemiological studies take advantage of the unfortunate fact that groups of people are already exposed to a wide variety of chemicals. The most fruitful studies are of occupational groups exposed to chemicals to which the general public is not exposed, or only at much lower levels. Studies of this type, for example, supplied the principal basis for identifying benzene as a cause of leukemia. The Infante study of workers in Ohio exposed to benzene in the manufacture of Pliofilm and numerous other studies discussed in the preamble to the benzene standard[57] demonstrate beyond doubt that benzene causes leukemia.

But epidemiological studies are relatively insensitive. Because of the small size of most occupational group studies, an effect generally will not be detected unless it is occurring in five to ten percent of the population. If the effect is relatively common, such as lung cancer, and has many chemical causes, an even greater response is needed from one chemical in order to be detected. For the most part, people are exposed to too many substances at unknown doses for unknown periods to permit the drawing

[56] DRINKING WATER AND HEALTH, *supra* note 43, at 39-47; Crump *et al.*, *supra* note 51.

[57] 43 Fed. Reg. 5918, 5925-32 (1978).

of statistically reliable conclusions from epidemiological studies about the magnitude of the risk.[58]

The same factors that render epidemiological studies insensitive as a means of identifying carcinogens make them extremely unreliable for quantifying the risks of the carcinogens they do identify.[59] Some of the most important factors are as follows.

First, sufficient latency periods often have not run to reveal the full effect. Latency in humans ranges from 15-40 years.[60] Second, dose information is often highly speculative, especially for periods of two or more decades ago, when exposure began. It is often difficult to determine even which workers in a factory were exposed, let alone at what level.[61] Third, not all exposed persons have been followed and their fate determined. Their illnesses and causes of death, or even whether they still live, is not determined. Since ill employees are the most likely to have left employ, the failure to follow them can seriously understate cancer incidence. Fourth, common cancers are often not related to their causes. Lung cancer, for example, appears to have many chemical causes. It is more difficult to relate this cancer to a specific chemical than one which is extremely rare and readily traced to a particular source.[62]

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[58] *See* Hoover, *supra* note 41; ENVIRONMENTAL CANCER, *supra* note 41.

[59] *See* sources in note 58, *supra*.

[60] COUNCIL ON ENVIRONMENTAL QUALITY, SIXTH ANNUAL REPORT 23 (1975).

[61] The benzene studies provide an example of this problem. See discussion at 43 Fed. Reg. 5927. Sometimes doses two or more decades past can be reconstructed only speculatively. For an effort to do such reconstruction, see Kramer & Mutchler, *The Correlation of Clinical and Environmental Measurements For Workers Exposed to Vinyl Chloride*, 33 AM. INDUS. HYGIENE ASS'N J. 19 (1972).

[62] *See* sources in note 58, *supra*.

c. *Animal Experiments Also Permit Identification of Carcinogens, But Not the Degree of Risk to Humans*

Lifetime studies on rodents are the major source of data on the carcinogenicity of chemicals. The animals' response to these chemicals is considered essentially similar to that of humans, so that a substance carcinogenic to one species is likely to be carcinogenic to the others. Nearly all of the chemicals whose human carcinogenicity has been proven epidemiologically have also been shown to cause cancer in animals. Most of the 65,000 chemicals in commerce pose no cancer risks. But there are at least several hundred chemicals that have been identified as carcinogens in animals, for which adequate epidemiological studies are unavailable.[63]

But animal studies cannot reliably indicate the magnitude of risks to people. To investigate directly the effects of the doses of carcinogen commonly experienced by people would require huge experiments. For example, to demonstrate with 95 percent confidence that a realistic dose of just one substance causes fewer than one cancer in a million subjects would require a test involving at least 6,000,000 animals. Such "mega-mouse" experiments would be impractically expensive.[64]

Scientists attempting to estimate the risks from commonly encountered doses use mathematical models of dose-response relationships to extrapolate from ex-

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[63] Tomatis, Agthe, Bartsch, Huff, Montesand, Saracci, Walker & Wilburn, *Evaluation of the Carcinogencity of Chemicals: A Review of the Monograph Program of the International Agency for Research in Cancer*, 38 CANCER RESEARCH 877 (1978); Saffiotti, *Identifying and Defining Chemical Carcinogens*, in ORIGINS OF HUMAN CANCER, *supra* note 41, at 1311.

[64] Mantel & Schneiderman, *Estimating "Safe" Levels, a Hazardous Undertaking*, 35 CANCER RESEARCH 1379, 1383 (1975).

perimental results on animals at higher doses. However, reflecting the lack of knowledge of precisely what is happening at and above the cellular level, the different models yield widely divergent estimates of the risk associated with each low dose. While the major mathematical models all agree with observed results, they can differ by a factor of 100,000 on the size of the dose that creates a risk of one cancer in a million animals.[65]

Our ignorance of how to translate dose-response estimates across species lines adds more uncertainties to risk estimates. Not enough is known to determine confidently the relative sensitivity of humans and each species or strain of test animals. For example, people are bigger than animals; there is uncertainty whether the proper way to scale up doses is on the basis of relative body weights or on the basis of relative surface areas of tissue.[66] Moreover, in contrast to human genetic heterogeneity and diverse chemical exposures, test animals are inbred for genetic homogeneity in order to facilitate uniform, reproducible test results, and they are generally exposed to only one substance at a time. Consequently, there may be subgroups of the human population far more sensitive than these inbred strains, and there may be interactions between chemicals that the animal tests do not reveal.[67]

Recent attempts by a committee of the National Academy of Sciences to quantify the risks from saccharin graphically illustrate the uncertainties. Using the results of the recent animal studies, the various plausible models,

[65] Cornfield, *Carcinogenic Risk Assessment*, 198 SCIENCE 693, 694 (1977).

[66] Rall, *Problems of Low Doses of Carcinogens*, 64 J. WASH. ACAD. SCI. 63 (1974). See also NAS SACCHARIN STUDY, *supra* note 47, at 3-68 to 3-72 and table 3-8.

[67] *See* DRINKING WATER AND HEALTH, *supra* note 43, at 35; SCHNEIDERMAN, MANTEL & BROWN, *From Mouse to Man—Or How to Get From the Laboratory to Park Avenue and 53rd Street*, 246 ANNALS OF THE N.Y. ACADEMY OF SCIENCES 237 (1975).

and the differing assumptions about how to cross species line to humans, they attempted to quantify the effects of a consuming one can of diet soda per day. The results suggested that in each 50 million people there could be as few as 0.0007 cancers per year or as many as 3640. This is a range of error more than 5,000,000-fold.[68]

2. *Techniques for Quantifying Economic Impact*

Forecasting the costs of controlling or avoiding exposure to a carcinogen is also difficult. Adequate control of carcinogens sometimes requires significant changes in equipment and operating procedures. The precise cost of improved measures to control exposure is difficult to determine, and the uncertainty increases with the degree of change. Moreover, as costs increase, consumers of the dangerous chemical tend to use less of it. They shift to safer chemicals or to other means of accomplishing the purpose the dangerous chemical serves. The magnitude of these effects and their economic value are extremely difficult to predict. Over time consumers (whether industries or individuals) adjust and learn new ways of satisfying their needs with less of a dangerous chemical or with none at all. Thus the actual costs may turn out to be smaller than first predicted after some time for innovation and adjustment.[69]

Moreover, objective analysis of economic impacts is hampered by the fact that often the parties with the most accurate information on the costs and effects of controlling a carcinogen have little incentive to make it available.[70] The industries making and using benzene, for example, have the best access to technological and eco-

[68] NAS SACCHARIN STUDY, *supra* note 47, at 3-72, table 3-8.

[69] The uncertainties are illustrated by graphs in W. ROWE, AN ANATOMY OF RISK 233-34 (1977).

[70] See NATIONAL ACADEMY OF SCIENCES, DECISION MAKING IN THE ENVIRONMENTAL PROTECTION AGENCY 51-58 (1977) [hereinafter cited as DECISION MAKING IN EPA]

nomic data to analyze the availability of substitutes and likely consumer responses, yet they may not feel that revealing it is in their commercial interest while a standard is under consideration.

An example illustrates the point. In 1974 the industries subject to the Secretary's standard for vinyl chloride stated that the one part per million standard for that carcinogen was technologically impossible to meet and that attempting to meet it would drive them into bankruptcy. The industries urged their positions without success before the Secretary, before the Second Circuit Court of Appeals,[71] and before this Court.[72] Yet within a month of the failure of their legal challenge, the companies began to announce dramatic technological advances and to drop their cost estimates to a fraction of their prior levels.[73] Polyvinyl chloride plastic today remains strongly competitive with other plastics despite compliance with the standard.[74]

3. *Comparing Health and Economic Interests*

There is no acceptable way of reducing health effects to dollars to allow comparison with the costs of controlling exposure. Economists have proposed a number of methodological approaches to such an evaluation.[75] But,

[71] *See* Society of the Plastics Industry v. OSHA, 509 F.2d 1301 (2d Cir. 1975), *cert. denied* 421 U.S. 992 (1975).

[72] *Id.*

[73] Greek, *Vinyl Chloride May Force Shortages by 1977*, CHEM. & ENGINEERING NEWS, Aug. 11, 1975, at 8, 9. *See also Goodrich Cuts Cost of Meeting VCM Limits*, CHEMICAL WEEK, Dec. 10, 1975, at 59.

[74] *PVC Rolls Out of Jeopardy, Into Jubilation*, CHEMICAL WEEK, Sept. 15, 1976, at 34.

[75] The various methods were surveyed and criticized by the Secretary in the preamble to his standard for coke oven emissions, 41 Fed. Reg. 46,750-51. For a concise summary of methods and problems, *see also* DECISION MAKING IN EPA, *supra* note 70, at 228-34.

none of the techniques can evaluate the questions of fairness which arise when the risks and benefits fall to different people, nor can they adequately evaluate the present value of preventing disease in the future.[76] In the end, they founder on the most basic ethical tenets, which turn away from consciously placing a monetary value on human life.

SUMMARY OF ARGUMENT

The Occupational Safety and Health Act empowers the Secretary of Labor to adopt highly protective standards in order to reduce the devastating toll of deaths, illnesses, and injuries in American workplaces. The Act places special emphasis on controlling exposure to chemicals that cause cancer and other fatal and disabling diseases among employees. Section 6(b)(5) of the Act directs the Secretary to set the standard for such a substance

> which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard . . . for the period of his working life.[77]

Congress recognized that with effects such as cancer, the hazards of chemicals in the workplace can be identified well before their precise magnitude can be known. Long latency periods, subtle cause-and-effect relation-

[76] *See generally* Baram, *Regulation of Health, Safety And Environmental Quality And The Use of Cost-Benefit Analysis*, Final Report to the Administrative Conference of the United States (1979); Fischhoff, *Cost-Benefit Analysis and the Art of Motorcycle Maintenance*, ~~43 Policy Analysis 64 (1977)~~ 8 Policy Sciences 177 (1977).

[77] 29 U.S.C. §655(b)(5).

ships, and complex interactions preclude having reliable *quantitative* data until long after the availability of reliable *qualitative* information. In the interim, because employees' lives and health are at stake, the Act permits—indeed requires—the Secretary to take action to prevent cancer, on the basis of such qualitative information, the best evidence then available.

By directing the Secretary to act on the basis of the best available evidence, the statute commits to him the determination of when, if ever, scientific knowledge has progressed sufficiently to allow reliable quantification. As long as he may reasonably determine such techniques are not yet reliable, the Act neither requires the Secretary to postpone taking protective action, nor demands that he undertake a sham quantitative analysis.

In this case, the Secretary has reasonably determined that quantitative risk assessment techniques do not reliably indicate the size of the cancer hazard. Accordingly, he concluded he must establish a standard for benzene, an undisputed carcinogen, using his best judgment about what is needed to protect employees, on the basis of the best qualitative evidence. He has not chosen to act blindfolded; rather, he has determined that quantitative risk assessment will not improve his vision.

Although the health of employees is the Secretary's paramount concern, Congress also recognized the need for practical considerations in setting standards. Consequently, the Act required the Secretary to set "feasible" standards. There is, however, nothing to support and much to refute the notion that the feasibility requirement, or any other provision of the Act, imposes on the Secretary the obligation to show through a quantitative analysis that the benefits of a standard outweigh its costs. Congress recognized the severe ethical and methodological limitations of such quantitative cost-benefit analysis. Not the least of these are the usual absence of reliable quantitative information about risks, and the absence of any acceptable way to place a dollar figure on the value of a life.

Despite the requirements and policies of the law, the lower court held that the Secretary may not adopt a standard to reduce the cancer hazard from benzene, unless he performs a quantitative assessment of the risk reduction to be gained, and provides a quantitative cost-benefit analysis demonstrating that these benefits bear a "reasonable relationship" to the costs to employers of complying with the standard.[78]

To reach its desired result, the court had to turn the terms and legislative history of the Occupational Safety and Health Act on their heads. Holding that "the best available evidence" and related phrases require quantitative risk assessment, the court imposed on them meanings exactly opposite to what their legislative history indicates.[79] Contrary to the court's conclusion, these phrases *require* preventive action while risks are still debated, rather than block it.

Recognizing it could find no support for quantitative cost-benefit in the term "feasible" or its legislative history, the court poured this meaning into an innocuous provision—"reasonably necessary" in the definition of standards—that Congress never contemplated would bear on the issue. The court also constructed a faulty parallel with the Consumer Product Safety Act.[80] The parallel would be of no help even if real, since the authors of the latter Act explicitly rejected quantitative cost-benefit analysis.

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[78] American Petroleum Inst. v. OSHA, 581 F.2d 493, 503 (5th Cir. 1978).

[79] *Id.* at 504.

[80] *Id.* at 502-03.

In its zeal to require quantitative risk assessment and cost-benefit analysis, the court bent the statutory "substantial evidence" test for review into a barrier to achievement of the Act's protective policies. While the court allowed that the Secretary's decision was *rational*, it held that without a quantitative risk assessment this was not enough.[81] To so read the substantial evidence test would cancel the Secretary's authority—clearly indicated by the remainder of the Act—to act on the basis of qualitative evidence when he reasonably determines that it is the best available.

The Fifth Circuit's decision conflicts with all other cases reviewing the validity of standards promulgated under the Occupational Safety and Health Act, from the District of Columbia, Second, Third, and Eighth Circuits. It would prevent the Secretary from effectively fulfilling his statutory mandate to protect employees from chemically-induced cancer and other killing and disabling diseases. It would place requirements on the Secretary that Congress did not impose, and that the Secretary reasonably determined were inappropriate. For these reasons, the decision should be reversed.

ARGUMENT

I. THE OCCUPATIONAL SAFETY AND HEALTH ACT DOES NOT REQUIRE QUANTITATIVE JUSTIFICATION FOR STANDARDS TO PROTECT EMPLOYEES FROM CANCER-CAUSING CHEMICALS

The Occupational Safety and Health Act particularly emphasizes standards to protect employees from cancer and other killing and disabling diseases caused by toxic

[81] *Id.* at 503.

chemicals and dusts in the workplace. Section 6(b)(5) directs the Secretary to set the standard

> which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws.[82]

Recognizing the long delays frequent between exposure to carcinogens and illness, the subtle nature of many cause-and-effect relationships, and the fact that employees' lives and health are at stake, Congress determined that a policy of minimizing exposure to these substances as much as feasible was the only one consistent with a prudent regard for public health. While obviously it would be desirable if more exact quantitative data were available on the risks of carcinogens and the costs of controlling them, the Occupational Safety and Health Act clearly reflects Congress' conclusion that the protection of public health from cancer-causing substances should not await the development of techniques needed to provide it. In effect, the Act represents a judgment that the potential human and economic costs to our nation of providing too little protection from this dread disease are too high to warrant awaiting more precise information, even though

[82] 29 U.S.C. §655(b)(5).

the standards the Secretary adopts may entail substantial expense, require technological innovation, or even cause significant economic change within an industry.

The lower court has proposed an entirely different approach from the precautionary one Congress adopted. It would prohibit the Secretary from adopting standards to protect employees from carcinogenic substances until he provided quantitative estimates of the reduction in risks associated with the proposed standard, and a quantitative analysis showing that the benefits outweighed the costs. This position, contrary to the understanding of all four of the other Courts of Appeal that have reviewed the validity of standards adopted under the Act, is as unwise a public health policy as it is contrary to the intention of the legislators who wrote the Act.

In attempting to justify its proclivity for quantification, the lower court could offer nothing more than a "*But see*" citation to the contrary decisions of the other circuits[83] and a lame assertion that the issues in those essentially identical cases were somehow different.[84] Similarly, it was forced to turn the Occupational Safety and Health Act inside out, disregarding the plain meaning and legislators' understanding of the terms Congress chose to address the proper manner of evaluating health evidence and the role of economic factors in standard-setting, while pouring its own notions of the role of costs and risk assessment into terms not meant to contain them.

At some point in the future, techniques for quantifying the magnitude of risks from workplace carcinogens and comparing the costs and benefits of alternative standards may be developed which are capable of increas-

[83] American Petroleum Inst. v. OSHA, 581 F.2d 493, 504 (5th Cir. 1978).

[84] *Id.* at 505.

ing the precision of occupational safety and health standards. But to this point Congress has not been persuaded, and the lower court has no power to substitute its own conclusions for those of the legislature.

A. Conditioning Standards on Quantitative Assessments of Risk Conflicts with the Congress' Desire to Prevent Disease Before It Develops.

Since cancer is a disease that resists a cure, preventing it is one of the most basic purposes of the Occupational Safety and Health Act. Thus the Act empowers—indeed requires—the Secretary to prevent exposure to carcinogens before they take their toll in human life. Since cancer is a disease that develops only after a long latency period and one whose mechanisms are not precisely known, prevention necessarily requires acting before all the data are available to assess precisely the magnitude of the risk. All too often, definite proof that a substance causes cancer, let alone evidence to assess the magnitude of its potency, can be found only after unacceptable damage to public health has already occurred—after some people have already contracted killing or disabling disease and many more have been irreversibly exposed.

It is abundantly clear in the Congressional debates accompanying the passage of the Occupational Safety and Health Act that Congress understood the import of these considerations and intended that action should occur without waiting until the numerical toll could be assessed.

1. The Primacy of the Goal of Preventing Occupationally-Caused Disease

The legislators who wrote the Occupational Safety and Health Act repeatedly stressed the seriousness of the problem of occupationally-induced disease, and their conclusion that rapid preventive action was both required and practical. Section 6(b)(5) reflects this urgency

throughout, requiring that each standard "most adequately assure[ ]," to the degree feasible, "that no employee will suffer material impairment of health or functional capacity," even after life-long exposure.[85] It requires the Secretary to seek "the highest degree of health and safety protection for the employee."[86]

Moreover, the statute directs the Secretary to act on "the best available evidence" and "the latest available scientific data in the field."[87] By these phrases, the House Report said, the legislators intended the Secretary to take preventive action promptly without waiting until the evidence necessary to determine the precise magnitude of the threat eventually becomes available: "The Committee feels it is vital that when the Secretary sets an occupational health standard he does so on the basis of the best available professional evidence; *it is not intended that the Secretary be paralyzed by debate surrounding diverse medical opinions.*"[88] By contrast, not a single Senator or Representative even suggested an intent to require quantitative assessment of the risks before the Secretary acted.

The legislative history of the Act shows that Congress clearly recognized the killing and disabling properties of a growing number of chemicals and dusts once thought to be safe, and the problems of latency and statistical subtlety that impede early discovery of the magnitude of risks.[89] These factors added urgency to taking protective,

[85] 29 U.S.C. §655(b)(5).

[86] *Id.* The references to "employee" in the singular emphasize the goal of protecting all employees, even those more sensitive than average. *See* HOUSE REPORT, *supra* note 15 at 18.

[87] 29 U.S.C. §655(b)(5).

[88] HOUSE REPORT, *supra* note 15, at 18 (emphasis added).

[89] *See e.g.*, Statement of Senator Saxbe, *reprinted in* SUBCOMM. ON LABOR OF THE SENATE COMM. ON LABOR AND PUBLIC WELFARE, LEGISLATIVE HISTORY OF THE OCCUPATIONAL SAFETY AND HEALTH ACT OF 1970 338-39 (1971) [hereinafter cited as LEG. HIST.].

preventive action as soon as a substance's dangers are identified, without waiting for years until the precise contours of the danger are fully researched.

The Senate Report on the bill emphasized the growing pattern of discovering life-threatening dangers even in familiar substances, as well as in the new chemicals of the post World War II period:

> [M]aterials long in industrial use are only now being discovered to have toxic effects. In addition, technological advances and new processes in American industry have brought numerous new hazards to the workplace. Carcinogenic chemicals, lasers, ultrasonic energy, beryllium metal, epoxy resins, pesticides, among others, all present incipient threats to the health of workers. Indeed, new materials and processes are being introduced into industry at a much faster rate than the present meager resources of occupational health can keep up with. It is estimated that every 20 minutes a new and potentially toxic chemical is introduced into industry. New processes and new sources of energy present occupational health problems of unprecedented complexity.[90]

The Report took especially seriously the developing edge of scientific knowledge on occupationally-induced disease:

> Recent scientific knowledge points to hitherto unsuspected cause-and-effect relationships between occupational exposures and many of the so-called chronic diseases—cancer, respiratory ailments, allergies, heart disease, and others. In some instances, the relationship appears to be

[90] SENATE REPORT, *supra* note 1, at 2.

> direct: asbestos, ionizing radiation, chromates, and certain dye intermediaries, among others, are directly involved in the genesis of cancer. In other cases, occupational exposures are implicated as contributory factors. The distinction between occupational and non-occupational illnesses is growing increasingly difficult to define.[91]

In addition, the Report observed that "the modern worker encounters health hazards involving complex, often synergistic interactions of numerous physical and chemical agents. . . ."[92]

The Committee cited the need to set standards forthwith to protect employees from the chemicals, metals, and dusts named above, as well as "ancient" poisons such as lead and mercury. The Committee did not consider quantification of the risk a precondition to regulation; employee protection from identified killers should not be postponed solely because their precise potency was uncertain.[93]

The House Report reiterated the same themes. It cited the dangers of these same chemicals and the rapidly growing knowledge of new dangers.[94] Moreover, the Committee stated:

> [W]orkers are in daily contact with literally hundreds of new chemicals and formulations about which little is known. As occupational health research becomes more sophisticated, there is every indication that the toxicity of the fumes, gases, and chemicals to which workers are exposed will be discovered by researchers.[95]

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[91] *Id.*
[92] *Id.* at 19.
[93] *Id.* at 2-4.
[94] HOUSE REPORT, *supra* note 15, at 14-15.
[95] *Id.* at 19.

As stated above, the House Committee emphasized that in setting standards for toxic substances, the Secretary must not be "paralyzed" by scientific uncertainties and differences of opinion.[96] He must resolve the uncertainties in favor of protecting the employees.

2. *Judicial Recognition of the Primacy of Preventing Disease*

Except for the Fifth Circuit, the Courts of Appeals that have reviewed OSHA standards for carcinogens have all correctly emphasized the law's requirement to take a precautionary, preventive view of the evidence of health harm. They have repeatedly upheld the Secretary's authority to set standards on the basis of qualitative evidence that identifies a substance as a carcinogen. Only the Fifth Circuit has sought to make quantifying the magnitude of risk a necessary prerequisite to protective action.

In *Industrial Union Dep't, AFL-CIO* v. *Hodgson*,[97] the District of Columbia Circuit upheld the standard for asbestos. The Secretary's knowledge of the effects of asbestos precisely paralleled his knowledge about benzene in the case under review here: he had firm evidence that asbestos was a carcinogen, although the precise effects of particular doses was not known. The court observed that the statute required the Secretary to base standards upon conclusions drawn from well-established data and from information "on the frontiers of scientific knowledge."[98] The court concluded:

> [I]n this case the evidence indicated that *reliable data is not currently available with respect to the precisely predictable health effects of various levels of exposure to asbestos dust; nevertheless, the Sec-*

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[96] *Id.* at 18.
[97] 499 F.2d 467 (D.C. Cir. 1974).
[98] *Id.* at 474.

> *retary was obligated to establish some specific level as the maximum permissible exposure.* After considering all the conflicting evidence, the Secretary explained his decision to adopt, over strong employer objection, a relatively low limit in terms of the severe health consequences which could result from over-exposure. *Inasmuch as the protection of the health of employees is the overriding concern of* [*the Act*], *this choice is doubtless sound. . . .*[99]

The Second Circuit faced the identical issue reviewing the standard for vinyl chloride. This chemical had been shown to cause cancer in workers exposed to relatively high doses (around 200 parts per million) and in animals at lower doses (down to 50 ppm). In *Society of the Plastics Industry* v. *OSHA*,[100] the court rejected the claim that the Secretary could not reduce exposures to one ppm without evidence of human harm down to that level. The court acknowledged that "though the factual finger points, it does not conclude."[101] Nonetheless, "Under the command of [the Act], it remains the duty of the Secretary to act to protect the workingman, and to act even in circumstances where existing methodology or research is deficient."[102]

The Third Circuit upheld the Secretary's standard for ethyleneimine, another carcinogen, in *Synthetic Organic Chemical Manufacturers Ass'n* v. *Brennan*,[103] on the basis of two animal studies and the judgment of committees of cancer experts that current knowledge showed no level of exposure to a carcinogen can be considered completely safe.[104] The court found no requirement that the Secretary be able

[99] *Id.* at 475 (emphasis added).

[100] 509 F.2d 1301 (2d Cir. 1975), *cert. denied*, 421 U.S. 992 (1975).

[101] *Id.* at 1308.

[102] *Id.*

[103] 503 F.2d 1155 (3rd Cir. 1974).

[104] *Id.* at 1157-61.

to quantify the risk. And in *American Iron & Steel Institute* v. *OSHA*,[105] the court held that the Secretary had ample evidence, from epidemiological studies of coke oven workers and expert opinion on the issue of safe doses for carcinogens, to conclude that coke oven emissions were carcinogenic and no level of exposure could be considered risk-free.[106]

The lower court decision is starkly inconsistent with those of its sister circuits. These courts have correctly perceived that statutory phrases such as "the best available evidence"[107] permit—even require—the Secretary to take protective action when he discovers that a substance is a carcinogen, without waiting for the development of the capability to quantify the magnitude of the threat to life. Yet the Fifth Circuit turned these phrases on their heads, interpreting them to *block* preventive action.[108] This reading ignores their plain meaning and the legislative history indicating that the very purpose of such

[105] 577 F.2d 825 (3rd Cir. 1978).

[106] *Id.* at 831-32.

[107] Occ. Safety & Health Act § 6(b), 29 U.S.C. §655(b)(5).

[108] American Petroleum Inst. v. OSHA, 581 F.2d 493, 504 (5th Cir. 1978). Besides "the best available evidence" and "the latest scientific data in the field," the court pointed to two other phrases in section 6(b)(5): "research, demonstrations, experiments, and such other information as may be appropriate," and "experience gained under other health and safety laws." If the last phrase indicates anything at all, it cuts against the lower court, for the weight of experience under other laws upholds the validity of the Secretary's approach to carcinogen regulation. *See e.g.*, Environmental Defense Fund v. EPA, — F.2d —, 8 ELR 20765 (D.C. Cir. 1978) (toxic water pollutants); Certified Color Mfrs. Ass'n v. Mathews, 543 F.2d 284 (D.C. Cir. 1976) (food color additives); Environmental Defense Fund v. EPA, 510 F.2d 1291 (D.C. Cir. 1975) (pesticides). As for "research . . . and such other information as may be appropriate," this phrase most fairly read envisions the use of just such epidemiological studies as the ones on which the Secretary relied.

phrases was to permit the Secretary to act to protect employees from known dangers without being "paralyzed" by the lack of scientific certainty on the extent of the hazard.[109] Yet rather than address the inconsistency of its position with the law and the other circuits, the court lamely refused even to discuss the contrary cases.[110]

In sum, the Act and the legislative history empower the Secretary not only to find facts about chemicals' toxicity, but also to make judgments where necessary to resolve scientific unknowns. The power to make such judgments is a necessary consequence of the Act's mandate that the Secretary set standards for chemicals identified as carcinogens. To be sure, the Secretary cannot regulate every existing substance simply because it might be harmful; he must have a firm basis for identifying a substance as dangerous, such as epidemiological or animal studies. But where *qualitative* identification of risk is best that can be done, Congress did not pose an impossible barrier to regulation.

Shortly after the decision in this case, the District of Columbia Circuit upheld toxic water pollutant standards for polychlorinated biphenyls (PCBs), which have produced cancer in laboratory animals. The court stated that when faced with claims of substantial economic impact,

> the temptation to demand that the agency furnish conclusive proof of carcinogenicity as support for the regulations is great. However, the decision to delegate authority to an agency to control suspected carcinogens is a legislative judgment that is not open to question in this court. Congress' direction to EPA to protect against incompletely understood dangers could not be carried out if we were to adopt the proof requirements advocated by industry petitioners.

[109] HOUSE REPORT, *supra* note 15, at 18.

[110] American Petroleum Inst. v. OSHA, 581 F.2d 493, 505 (5th Cir. 1978).

> What scientists know about the causes of cancer is how limited is their knowledge. The record in this case demonstrates that it may take decades for human exposure to carcinogens to result in cancer; in the meantime, the case for inferring a cancer danger with respect to an incompletely understood substance is vigorously disputed. If regulation were withheld until the danger was demonstrated conclusively, untold injury to public health could result.[111]

The Fifth Circuit has succumbed to this temptation and substituted its judgment for that of Congress.

B. The Requirement that Standards be Feasible Does Not Mandate a Quantitative Demonstration that their Benefits Exceed Their Costs.

While the purpose of the Occupational Safety and Health Act was to decrease drastically the incidence of workplace-induced disease, its authors recognized that practicality imposed limits on the achievement of this goal. Thus in section 6(b)(5) they limited the measures that the Secretary might require to reduce exposure to cancer-causing substances to those that were "feasible." While the use of the term feasibility obviously implies that the Secretary must consider the economic cost of proposed regulations to employers when he adopts workplace exposure standards for carcinogens, the legislative history demonstrated that Congress did not intend the consideration of economic costs to impede vigorous action to prevent occupationally-induced disease. In short, while recognizing that a wholly risk-free working environment might not always be practical, the legislators did not

[111] Environmental Defense Fund v. EPA, —F.2d—, —, 8 ELR 20765, 20780 (D.C. Cir. 1978).

contemplate an unrealistic quantitative demonstration that the benefits of a proposed standard outweighed its costs to industry.

1. ***The Legislative History Of The Term "Feasible" Shows That Congress Intended Only A Limited Role For Cost Considerations In Setting Standards***

Section 6(b)(5) directs the Secretary to set standards that prevent impairment of employees' health "to the extent feasible."[112] The legislative history shows that all congressional discussion of the role of economic considerations in setting standards was structured around this feasibility requirement. Nothing in this provision or its legislative history can be construed as requiring quantitative cost-benefit analysis.

Tracing the meaning of the feasibility requirement begins with the bill reported by the House Committee in July 1970.[113] This bill, the so-called Daniels bill, would have established the employees' right to standards providing fully safe workplaces without any qualification:

> The Secretary, in promulgating standards under this subsection, shall set the standard which most adequately assures, on the basis of the best available professional evidence, that no employee will suffer any impairment of health or functional capacity, or diminished life expectancy, even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.[114]

The Senate Committee, which reported a bill several months later, added the feasibility requirement to the

[112] 29 U.S.C. §655(b)(5).

[113] H.R. 16785, *reprinted in* HOUSE REPORT, *supra* note 15, at 1-14.

[114] *Id.* §7(a)(4).

Daniels formulation. As reported, Section 6(b)(5) attained its nearly final form:

> The Secretary, in promulgating standards under this subsection, shall set the standard which most adequately *and feasibly* assures, on the basis of the best available evidence, that no employee will suffer any impairment of health or functional capacity, or diminished life expectancy even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of such standards shall be based on research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, *the feasibility of the standards*, and experience gained under this and other health and safety laws.[115]

The feasibility requirement was added in committee at the suggestion of Senator Javits, one of the principal architects and managers of the bill. He explained the amendment in his individual views attached to the Report:

> As a result of this amendment the Secretary, in setting standards, is expressly required to consider feasibility of proposed standards. This is an improvement in the Daniels bill, which might be interpreted to require absolute health and safety in all cases, regardless of feasibility, and the Administration bill, which contains no criteria for standards at all.[116]

[115] S. 2193 §6 (b)(5) (Oct. 5, 1970), *reprinted in* LEG. HIST., *supra* note 89, at 242 (emphasis added).

[116] SENATE REPORT, *supra* note 1, at 58.

The Senate Report reiterated that "standards promulgated under section 6(b) shall represent feasible requirements. . . ."[117]

The comments of Senator Javits in the Committee Report,[118] and a colloquy on the Floor between Senators Williams and Dominick over the final fine-tuning amendment to section 6(b)(5),[119] show that Congress recognized completely risk-free workplaces might not always be possible to achieve. The feasibility limit was intended to free the Secretary from the duty to set absolutely safe standards in those situations. Congress also recognized that it would not make sense to protect employees by eliminating their jobs in a wholesale manner. But these legislators' statements, and many others in the Senate and House Reports and floor debates, also underscore that the standards must drastically reduce the intolerably high rates of work-related deaths, illnesses, and injuries.[120] Congress recognized that sometimes adequate protection

[117] *Id.* at 7.

[118] *Id.* at 58.

[119] Amendment No. 1058, *reprinted in* LEG. HIST., *supra* note 89, at 502-03 (colloquy between Senators Williams and Dominick). In his original remarks on this subject, Senator Dominick missed the point of Senator Javits' feasibility amendment in committee, which was to relieve the Secretary of the obligation to set standards guaranteeing complete safety in all cases. *Id.* at 480-82 (remarks of Senator Dominick.) But after changing the Committee's "most adequately and feasibly assures" to the final version's "most adequately assures, to the extent feasible," (thereby expressing feasibility syntactically as a limitation but not changing meaning), Senators Dominick, Javits, and Williams came to full accord. *Id.* at 502-03.

[120] *See e.g.*, SENATE REPORT, *supra* note 1, 2-4; HOUSE REPORT, *supra* note 15, at 14-16. *See also*, LEG. HIST., *supra* note 89, at 411-14 (remarks of Sen. Williams), 509-11 (remarks of Sen. Yarborough), 512-13 (remarks of Sen. Muskie), 518 (remarks of Sen. Nelson), 522 (remarks of Sen. Cranston), 985 (remarks of Rep. Perkins), 1212 (remarks of Rep. Daniels).

would entail substantial expense and sometimes would even result in closing some businesses.[121] As Senator Eagleton stated, the costs of assuring such protection must be borne as "necessary costs of doing business." He added: "[W]e can no longer permit profits to be dependent upon an unsafe or unhealthy worksite."[122]

The legislative history contains not a single statement by any member of the House or Senate suggesting that decisions should be reached through quantitative cost-benefit analysis. Indeed, the legislative history reveals a strong hostility to this approach, particularly to the idea of putting a dollar price on human life. As Senator Yarborough, then chairman of the full committee that reported the bill, stated: "We are talking about people's lives, not the indifference of some cost accountants."[123]

2. *Prior Cases Have Concluded That Costs Are To Be Accorded a Limited Role in Setting Standards*

The cases reviewing standards prior to *American Petroleum Institute* were unanimous that the requirement that standards be feasible is the limit of economic concern in the Act. The District of Columbia, Second, and Third Circuits all upheld the Secretary's "lowest feasible level" approach to setting standards for carcinogens. In addition, the Third and Eighth Circuits specifically rejected claims that the Act requires quantitative cost-benefit analysis.

[121] Both the Senate and House Committees contemplated that some substances were simply too dangerous to remain in use. *See* discussion of betanapthylamine, a very potent carcinogen, SENATE REPORT, *supra* note 1, at 4; HOUSE REPORT, *supra* note 15, at 15. *See also* the statement by Senator Saxbe: "It is a real question to me as to whether asbestos can be used at all, whether it can be handled," *reprinted in* LEG. HIST., *supra* note 89, at 338.

[122] LEG. HIST. at 1150-51 (remarks of Sen. Eagleton).

[123] *Id.* at 510 (remarks of Sen. Yarborough).

In *Industrial Union Dep't, AFL-CIO* v. *Hodgson*,[124] reviewing the asbestos standard, the District of Columbia Circuit stated: "There can be no question that [the Act] represents a decision to require safeguards for the health of employees even if such measures substantially increase production costs."[125] The court recognized that feasibility imposed a practical limit on standards. Citing Senator Javits' comments in the Committee Report, the court stated:

> The thrust of these remarks would seem to be that practical considerations can temper protective requirements. Congress does not appear to have intended to protect employees by putting their employers out of business—either by requiring protective devices unavailable under existing technology or by making financial viability generally impossible.[126]

On the other hand, short of this drastic result the costs of employee protection must be borne. When lives are at stake, standards cannot be restricted to the lowest common denominator that the most recalcitrant employer will [redacted] accept:

> Standards may be economically feasible even though, from the standpoint of employers, they are financially burdensome and affect profit margins adversely. Nor does the concept of economic feasibility necessarily guarantee the continued existence of individual employers. It would appear to be consistent with the purposes of the Act to envisage the economic demise of an employer who has lagged behind the rest of the

[124] 499 F.2d 467 (D.C. Cir. 1974).
[125] *Id.* at 477.
[126] *Id.* at 477-78.

> industry and is consequently financially unable to comply with new standards as quickly as other employers.[127]

The court opined that extreme burdensomeness might be reason for phasing requirements in over some lead time.[128] But it did not suggest even extremely burdensome standards could never be imposed. Moreover, the court emphasized that the Act did not permit the Secretary to delay standards "needlessly."[129]

In *Society of the Plastics Industry* v. *OSHA*,[130] reviewing the standard for another carcinogen, vinyl chloride, the Second Circuit, Justice Clark writing, articulated the technology-forcing character of the Act:

> In the area of safety, we wish to emphasize, the Secretary is not restricted by the status quo. He may raise standards which require the development of new technology, and he is not limited to issuing standards based solely on devices already fully developed.[131]

In *AFL-CIO* v. *Brennan*,[132] the Third Circuit agreed that standards may require technological innovation and may alter the economic status quo. The court stated that although standards must be feasible,

> we agree with the Second Circuit in *Society of Plastics* . . . that, at least to a limited extent, [the Act] is to be viewed as a technology-forcing piece of legislation. Thus the Secretary would

[127] *Id.* at 478 (footnote omitted).
[128] *Id.*
[129] *Id.* at 479.
[130] 509 F.2d 1301 (2d Cir. 1975), *cert. denied* 421 U.S. 992 (1975).
[131] *Id.* at 1309.
[132] 530 F.2d 109 (3rd Cir. 1975).

> not be justified in dismissing an alternative to a proposed health and safety standard as infeasible when the necessary technology looms on today's horizon.[133]

The Third Circuit also held that imposing substantial costs on industry was contemplated within the notion of feasibility. It held that standards need not be limited to the lowest common denominator that all employers in an industry will accept: "Congress did contemplate that the Secretary's rulemaking would put out of business some businesses so marginally efficient or productive as to be unable to follow standards otherwise universally feasible."[134] Moreover, the court suggested that some work was too dangerous to be permitted, especially if economic consequences of doing without such activities were relatively mild:

> We do not question that there are industrial activities involving hazards so great and of such little social utility that the Secretary would be justified in concluding that their total prohibition is proper if there is no technologically feasible method of eliminating the operational hazard.[135]

In *American Iron and Steel Institute* v. *OSHA*,[136] the Third Circuit reiterated this approach, upholding the feasibility of the standard to control carcinogenic coke oven emissions. The court held that the Act permitted the Secretary to base the standard on the performance of the best plant in operation and on improvements that could be reasonably forecast in its performances, by using additional technology in use elsewhere or "looming on today's

[133] *Id.* at 121 (citation and footnote omitted).
[134] *Id.* at 123 (footnote omitted).
[135] *Id.* at 121.
[136] 577 F.2d 825 (3rd Cir. 1978).

horizon."[137] The court upheld the Secretary's conclusion that the cancer hazard warranted the cost of the standard, which the employers admitted they could bear without significant disruption.[138] Moreover, the court approved the Secretary's rejection of quantitative cost-benefit analysis.[139]

The Eighth Circuit also explicitly rejected quantitative cost-benefit analysis in *Arkansas-Best Freight Systems* v. *Occ. Safety & Health Rev. Comm'n.*[140] The court quoted with approval the discussion of feasibility in *Industrial Union Dep't* and added: "The Act does not attempt to balance as neatly as does Arkansas-Best the costs of compliance against the cost of employees' injuries."[141] The court held that the standard there in question was within the Secretary's legislative grant of power "to protect the health of employees even though increased production costs may result."[142]

These four courts found nothing in the statute's notion of feasibility or any other provision of the Act to require quantitative risk assessment or cost-benefit analysis. In this regard they stand in stark contrast to the decision here under review. In this case the Fifth Circuit did not even dispute the other courts' understanding of the notion of feasibility. Recognizing the hopelessness of finding support for its quantitative requirements in this term, the court merely brushed it away. In an act of pure judicial legislation the court poured its quantitative requirements into the unwilling vessel of the phrase "reasonably necessary" in section 3(8). But this provision offers the court no support either.

[137] *Id.* at 833-35.
[138] *Id.* at 836-37.
[139] *Id.* at 836.
[140] 529 F.2d 649 (8th Cir. 1976).
[141] *Id.* at 654.
[142] *Id.* at 653.

C. The Lower Court Erred In Holding That Quantitative Cost-Benefit Analysis Is Mandated by the Requirement that Standards Be "Reasonably Necessary."

Section 3(8)[143] supplies no additional requirements regarding the role of economic considerations in setting standards. Instead, it merely means that the measures the Secretary includes in a standard must be rationally connected to alleviating the hazard at which the standard is aimed.

1. *The Legislative History Shows That "Reasonably Necessary" Has No Bearing On The Role Of Cost Considerations*

In contrast to the extensive legislative history on the feasibility requirement, section 3(8) received absolutely no discussion. It was an innocuous, uncontroversial provision common to every bill introduced on occupational safety and health in the 91st Congress.[144] Some of these bills differed substantially on the role of economic considerations. Yet all bills defined standards the same way. Thus the legislators could not have understood this provision to bear at all on this issue, let alone to create a quantitative cost-benefit analysis requirement.

The comments of Senator Javits, one of the legislators most concerned to assure that the Secretary would consider economic aspects of standards, make this clear. Despite the fact that all bills contained the "reasonably necessary" provision, Javits stated that without the feasibility amendment the Daniels bill "might be interpreted to require absolute health and safety in all cases," and the

[143] 29 U.S.C. §652(8).

[144] Each bill introduced into the 91st Congress defined occupational safety and health standards as requirements either "reasonably necessary" or "reasonably necessary or appropriate" to provide safe or healthful employment and places of employment. *See* the bills collected in LEG. HIST., *supra* note 89.

Administration bill would "contain[ ] no criteria for standards at all."[145] If he had attached *any* importance to section 3(8), Javits could not have reached this conclusion.

2. *"Reasonably Necessary" Merely Requires A Rational Connection Between The Means And Objectives of Standards*

Section 3(8) has a far more natural meaning than the lower court wished to force upon it. By defining standards as measures "reasonably necessary or appropriate" to provide safe or healthful workplaces, this provision merely requires the Secretary to show that measures have a rational connection to reducing the hazard at which the standard is aimed. Thus, it prohibits the Secretary from imposing patently unnecessary or irrelevant requirements, such as fire-fighting equipment for dealing with a non-flammable substance. There can be no serious contention that this lenient test of relevance requires the Secretary to quantify cancer risk. This conclusion would negate the precautionary approach so clearly indicated by the remainder of the statute and its legislative history.

D. The Consumer Product Safety Act Does Not Support The Lower Court's Construction Of The Occupational Safety and Health Act.

Unable to find any support for quantitative cost-benefit analysis in the Occupational Safety and Health Act or its legislative history, the court turned to a completely independent statute adopted two years later. The court asserted that section 3(8) is identical to certain provisions in the Consumer Product Safety Act,[146] which the court further asserted require quantitative cost-benefit analysis. Neither assertion is correct.

[145] SENATE REPORT, *supra* note 1, at 58.

[146] 15 U.S.C. §§2051-2081.

1. *The Two Acts Are Not Parallel*

Section 3(8) of the Occupational Safety And Health Act defines standards as measures "reasonable necessary or appropriate to provide safe or healthful employment."[147] Sections 7(a) and 9(c)(2)(A) of the Consumer Product Safety Act (CPSA) limit standards under that Act to requirements "reasonably necessary to eliminate or reduce an unreasonable risk of injury".[148] Comparing these provisions, the court stated: "We decline to construe the precisely similar requirements of these two Acts differently or to read words out of the OSHA legislation."[149] In fact, the provisions are not "precisely similar," and the court has read words *into* the Occupational Safety and Health Act.

The court failed to comprehend that "unreasonable risk," not "reasonably necessary," is the phrase which establishes the obligation to consider costs in the CPSA. This is clearly evident in the CPSA legislative history.[150] The phrase "unreasonable risk" is pointedly absent from the Occupational Safety and Health Act. So rather than read "reasonably necessary" *out* of the Act, the court has read "unreasonable risk" *in*.

2. *The Consumer Product Safety Act Does Not Require Quantitative Cost Benefit Analysis*

Even if the CPSA were parallel to the Occupational Safety and Health Act, it would provide the lower court no support, because the CPSA does not require quantitative cost-benefit analysis. The House Report on this statute specifically rejected cost-benefit analysis as an element of

[147] 29 U.S.C. §652(8).

[148] 15 U.S.C. §§2056(a), 2058(c)(2)(A).

[149] American Petroleum Inst. v. OSHA, 581 F.2d 493, 502 (5th Cir. 1978).

[150] *See* H.R. REP. NO. 1153, 92d Cong., 2d Sess. 33 (1972) (House Report on Consumer Product Safety Act).

determining "unreasonable risk." The committee made clear that the Commission must consider the traditional elements of the tort law reasonableness test: the probability and gravity of harm and the effect of regulation on the product's utility, cost, or availability.[151] The committee then added the following explicit caveat: "There should be no implication, however, that in arriving at its determination the Commission would be required to conduct and complete a cost-benefit analysis prior to promulgating standards under this Act."[152] Thus, even in enacting "unreasonable risk" statutes Congress recognizes that formal, quantitative techniques are not adequate to the decision-making task.

The rejection of quantitative cost-benefit analysis for determining "unreasonable risk" is by no means an anomaly of the CPSA. For example, Congress reached the same conclusion in enacting the Toxic Substances Control Act[153] in 1976. The House Report stated:

> During the hearings a number of witnesses recommended that the bill include a definition of unreasonable risk. Because the determination of unreasonable risk involves a consideration of probability, severity, and similar factors *which cannot be defined in precise terms and is not a factual determination but requires an exercise of judgment on the part of the person making it*, the Committee did not attempt a definition of such risk. In general, a determination that a risk associated with a chemical substance or mixture is unreasonable involves balancing the probability that harm will occur and the magnitude and severity of that harm against the effect of pro-

[151] *Id.*

[152] *Id.*

[153] 15 U.S.C. §§2601-2629.

posed regulatory action on the availability to society of the benefits of the substance or mixture, taking into account the availability of substitutes . . . and other adverse effects which such proposed action may have on society.

The balancing process described above *does not require a formal benefit-cost analysis under which a monetary value is assigned to the risks associated with the substance and to the cost to society of proposed regulatory action on the availability of such benefits. Because a monetary value often cannot be assigned to a benefit or cost, such an analysis would not be very useful.*[154]

The fact that these "unreasonable risk" statutes explicitly reject quantitative cost-benefit analysis makes the lower court's attempt to use them to shoehorn quantitative analysis into the Occupational Safety and Health Act even less plausible.

II. THE SECRETARY ACTED WELL WITHIN HIS DELEGATED AUTHORITY IN DECLINING TO ADOPT QUANTITATIVE RISK ASSESSMENT

The Occupational Safety and Health Act establishes the basic criteria for standards for toxic substances: the

[154] H.R. REP. NO. 1341, 94th Cong., 2d Sess. 13-14 (1976) (footnote omitted, emphasis added), The footnote quoted from an influential study on chemical regulation and decision making:

> *Highly formalized methods of benefit-cost analysis can seldom be used for making decisions about regulating chemicals in the environment. Thus the development of such methods should not have high priority.*

NATIONAL ACADEMY OF SCIENCES, DECISION MAKING FOR REGULATING CHEMICALS IN THE ENVIRONMENT 44 (1975) (emphasis in original).

goal of no impairment of health, the duty to take preventive action on the basis of the best available evidence, and the constraint of feasibility.[155] But within the bounds of these criteria, the Act delegates to the Secretary substantial responsibilities to determine which substances shall be covered by standards and what requirements such standards shall contain.

In this case, the Secretary determined from repeated epidemiological studies that benzene causes leukemia in humans. He also concluded that there was very little margin, if any at all, between the benzene levels at which the chemical had already been shown to induce leukemia in humans and the existing 10 parts per million (ppm) standard, which had been developed years before and was aimed only at benzene's non-malignant effects.

Relying on the best expertise among cancer scientists, the Secretary determined that a safe level of human exposure to a carcinogen cannot be demonstrated, and that the size of the cancer risk at particular doses cannot now be established with any useful precision. He concluded, however, that a 90 percent reduction in exposure would significantly reduce employees' risks, and that such a reduction was feasible. Consequently, he set the new standard at one ppm.

The Secretary's decision was well within the statutory criteria that bound his delegated authority. His determinations were supported by both the best available scientific evidence and expertise. The basis for each of his judgments was well represented in the record of the decision.

In cases with essentially identical issues and records, the three other Courts of Appeals to review the Secretary's carcinogen standards have respected the Secre-

[155] Occ. Safety & Health Act § 6(b)(5); 29 U.S.C. § 655(b)(5).

tary's expertise and his mandate and upheld his decisions.[156] On the issue of quantifying risk, they have respected his expert judgment that the quantitative techniques are not sufficiently precise or reliable to be useful in determining standards. In fact, these courts have recognized that the Secretary would exceed his authority if he delayed acting until cancer risks could be reliably quantified, since the statute mandates standards to protect employees from life-threatening hazards on the basis of qualitative evidence when that is the best available.

The lower court in this case, however, held that unless the Secretary showed quantitatively the amount by which the new benzene standard would reduce the employees' cancer hazard, his decision could not be supported by substantial evidence.[157] With this holding, the lower court simply substituted its judgment for the Secretary's on the question whether benzene's cancer risk at particular doses can be reliably quantified. But the decision whether these techniques are sufficiently reliable that they constitute an appropriate basis for determining permissible exposure levels to carcinogens is a judgment committed to the Secretary, to which, if adequately supported and rational, the courts must defer. The lower court's drastic overestimation of the accuracy and reliability of the techniques for quantifying risk classicly illustrates the dangers of appellate judges' venturing into areas requiring detailed knowledge of a highly complex body of scientific study and thought.

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[156] Industrial Union Dep't, AFL-CIO v. Hodgson, 499 F.2d 467 (D.C. Cir. 1974); Society of the Plastics Industry v. OSHA, 509 F.2d 1301 (2d Cir. 1975), *cert. denied* 421 U.S. 992 (1975); Synthetic Organic Chemical Mfrs. Ass'n v. Brennan, 503 F.2d 1155 (3rd Cir. 1974); American Iron & Steel Inst. v. OSHA, 577 F.2d 825 (3rd Cir. 1978).

[157] American Petroleum Inst. v. OSHA, 581 F.2d 493, 503 (5th Cir. 1978).

A. The Substantial Evidence Test Does Not Permit The Court To Substitute Its Judgment For The Secretary's On The Reliability Of Quantitative Risk Assessments

1. *Standard Setting Under The Occupational Safety And Health Act Involves A Mixture Of Fact-Finding And Policy-Making*

The Secretary's determination in setting standards for carcinogens under section 6(b)(5) consist of both fact-finding and policy-making. He begins with a core of well-established facts about a chemical's toxicity. In this instance, epidemiological studies establish firmly that benzene causes leukemia. But his inquiry does not end with traditional fact-finding, because the solid facts do not supply the complete picture. The Act mandates that the Secretary take preventive action on the best available evidence.[158] This means that he must take into [redacted] consideration the qualitative but not completely precise evidence of harm, and, relying on the best scientific expertise, resolve the uncertainties as to the magnitude of the cancer risk in the manner that most protects employees' health.

These determinations to resolve scientific uncertainties are essentially policy judgments. The power to make these policy judgments is a necessary consequence of the Act's mandate to protect employees from identified hazards on the basis of the best available evidence. Restricted to traditional fact-finding, the Secretary would only be able to protect workers from the doses of carcinogens that already have been shown to kill, despite the strong but not completely certain belief that lower doses are dangerous too. The Secretary necessarily must have the most discretion to make such protective policy judg-

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[158] Occ. Safety & Health Act § 6(b)(5), 29 U.S.C. § 655(b)(5).

ments with regard to the most serious health effects, such as cancer, and in situations where difficulties in precisely pinning down the risks are greatest.[159]

The determinations that safe doses of carcinogens cannot be identified, that lower doses are safer than higher ones, and that risks cannot be reliably quantified are mixed conclusions of fact and policy. They have a firm base in observed facts, supplemented by scientific theory of the processes of cancer. Ultimately, however, they rest on the judgments guided by the policy of the Act to resolve doubts about safety in the employees' behalf.

2. *The Substantial Evidence Test Does Not Prohibit The Secretary From Making Policy Judgments*

The Occupational Safety and Health Act provides for basically informal rulemaking of the kind traditionally associated with policy-setting. Section 6(b) provides for notice-and-comment procedures, supplemented with an opportunity for a public hearing.[160] Section 6(e) requires the Secretary to accompany standards with a statement of reasons.[161]

This statute was one of the first to combine informal rulemaking with the substantial evidence test for judicial review, which is specified by section 6(f).[162] Interpreting

[159] The feasibility limitation does not detract from the duty to take a precautionary view of the evidence. Rather, the Secretary must take feasibility considerations into account only after appraising the risk, on the basis of the best available evidence. One must keep distinct the process of determining what risk *exists* from the process of determining what risk *will be tolerated*.

[160] 29 U.S.C. § 655(b)(1)-(4).

[161] *Id.* § 655(e).

[162] *Id.* § 655(f).

this "anomalous combination,"[163] the courts reviewing standards set under section 6(b)(5), with the exception of the Fifth Circuit, have correctly perceived their role as having a dual aspect. With respect to factual issues, they must assure that the Secretary's determinations are supported by substantial evidence. But they have understood that the test cannot be interpreted to bar the Secretary from making policy judgments that the provision of informal rulemaking and the substantive mandates of the Act so clearly indicate he must make. Consequently, with respect to issues "on the frontiers of scientific knowledge,"[164] these courts have recognized that the Secretary's duty is to explain the reasoning he uses to resolve uncertainties and to show that this reasoning is consistent with the protective policies of the Act. The essential task of the courts as to these issues is to assure that the Secretary acted rationally.

The District of Columbia Circuit, Judge McGowan writing, appropriately stated the Secretary's task and the court's role in *Industrial Union Dep't, AFL-CIO* v. *Hodgson*:[165]

> From extensive and often conflicting evidence, the Secretary in this case made numerous factual determinations. With respect to some of those questions, the evidence was such that the task consisted primarily of evaluating the data and drawing conclusions from it. The court can review that data in the record and determine whether it reflects substantial support for the Secretary's findings. But some of the questions

[163] The combination was so characterized in Industrial Union Dep't, AFL-CIO v. Hodgson, 499 F.2d 467, 473 (D.C. Cir. 1974). The legislative history leading to this combination is traced in Associated Industries of N.Y.S. v. United States Dep't of Labor, 487 F.2d 342, 347-50 (2d Cir. 1973) (Friendly, J.).

[164] *Industrial Union Dep't*, 499 F.2d at 474.

[165] *Id.*

> involved in the promulgation of these standards are on the frontiers of scientific knowledge, and consequently as to them insufficient data is presently available to make a fully informed factual determination. Decision making must in that circumstance depend to a greater extent upon policy judgments and less upon purely factual analysis. Thus, in addition to currently unresolved factual issues, the formulation of standards involves choices that by their nature require basic policy determinations rather than resolution of factual controversies. Judicial review of inherently legislative decisions of this sort is obviously an undertaking of different dimensions.
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> . . .
>
> Policy choices of this sort are not susceptible to the same type of verification or refutation by reference to the record as are some factual questions. Consequently, the court's approach must necessarily be different no matter how the standards of review are labeled.[166]

The court sensitively summarized the Secretary's obligation as follows:

> What we are entitled to at all events is a careful identification by the Secretary, when his proposed standards are challenged, of the reasons why he chooses to follow one course rather than another. Where that choice purports to be based

[166] *Id.* at 474-75 (footnotes omitted). In one of the footnotes the court stated: "Where existing methodology or research is deficient, the agency necessarily enjoys broad discretion to attempt to formulate a solution to the best of its ability on the basis of available information." *Id.* at 474 n. 18, *citing* Permian Basin Area Rate Cases, 390 U.S. 747, 811 (1968).

> on the existence of certain determinable facts, the Secretary must, in form as well as substance, find those facts in the record. By the same token, when the Secretary is obliged to make policy judgments where no factual certainties exist or where facts alone do not provide the answer, he should so state and go on to identify the considerations he found persuasive.[167]

Judge McGowan's view has been cited with approval by this Court. *Federal Communications Comm'n* v. *National Citizens Committee for Broadcasting*, 436 U.S. 775, 814 (1978).

Moreover, this view has been explicitly sanctioned by Congress. Congress has adopted the combination of basically informal rulemaking and the substantial evidence test in several subsequent health, safety, and environmental protection statutes.[168] An example is the 1976 Toxic Substances Control Act;[169] its legislative history on judicial review expressly endorses the approach of *Industrial Union Dep't.*[170] Congress has determined to continue using this combination in laws dealing with highly technical areas where there is substantial scientific uncertainty, even for the experts. As the District of Columbia Circuit recognized, the achievement of the Act's purposes is inseparable from and dependent on the Secretary's power to make policy judgments to resolve uncertainties, and the Secretary's actions must not be reviewed in a manner that frustrates action "where facts alone do

[167] 499 F.2d at 475-76.

[168] *E.g.*, Consumer Product Safety Act, 15 U.S.C. §§ 2056, 2060(c); Toxic Substances Control Act, 15 U.S.C. §§ 2605(c), 2618.

[169] *Id.*

[170] *See* H.R. Rep. No. 1341, 94th Cong., 2d Sess. 55-56 (1976) (House Report). The Committee paraphrased Judge McGowan's statement with approval.

not provide the answer."[171] Other courts have adopted this formulation of their review task, or have reached functionally similar formulations that require the Secretary to demonstrate the reasonableness or rationality of his policy judgments but do not block him from accomplishing the statute's purposes.[172]

Other than the Fifth Circuit, the courts have also come to understand that, at least in these highly technical subject areas, there is little, if any, meaningful difference

[171] 499 F.2d at 476.

[172] Judge Friendly's analysis in *Associated Industries* for the Second Circuit is quoted in note 173, *infra*. Also for the Second Circuit, Justice Clark adopted the District of Columbia Circuit's formulation. Society of the Plastics Industry v. OSHA, 509 F.2d 1301, 1303-04 (2d Cir. 1975), *cert. denied* 421 U.S. 992 (1975).

The Third Circuit has stated a five-part formulation of its review function. The principle ones bearing on this issue are whether the Secretary has adequately set forth his reasons, whether his reasons reflect "consideration of factors relevant under the statute," whether he considered "presently available alternatives," and, if his determination is based "in whole or in part on factual matters subject to evidentiary development, whether substantial evidence in the record as a whole supports the determination." Synthetic Organic Chemical Mfrs. Ass'n v. Brennan, 503 F.2d 1155, 1160 (3rd Cir. 1974). *See also* American Iron & Steel Inst. v. OSHA, 577 F.2d 825, 830-31 (3rd Cir. 1978).

Even the Fifth Circuit's formulation, although not its *practice*, is consistent with these. After reviewing these approaches, the court stated: "[I]t seems clear that even with the required substantial evidence test, our review basically must determine whether the Secretary carried out his essentially legislative task in a manner reasonable under the state of the record before him." American Petroleum Inst. v. OSHA, 581 F.2d 493, 497 (5th Cir. 1978), *quoting from* Florida Peach Growers Ass'n v. United States Dep't of Labor, 489 F.2d 120, 129 (5th Cir. 1974). In practice, this court substituted its judgment for the Secretary's expert conclusion that quantitative risk assessments for carcinogens are too unreliable to be the basis of standard-setting.

between the substantial evidence test and the arbitrary and capricious test normally applied to rulemaking. The tests have converged to a point where any remaining theoretical distinction between them simply is not administrable.[173] The essential function of review under either test is to assure that the agency has taken into account

[173] See *e.g.*, Associated Industries of N.Y.S. v. United States Dep't of Labor, 487 F.2d 342 (2d Cir. 1973) (Friendly, J.):

> While we have felt constrained to determine and sustain the applicability of the substantial evidence test, it may well be that the controversy is semantic in some degree, at least in the context of informal rulemaking, and that it lacks the dispositional importance that respondents imply .... In WBEN, Inc. v. United States ..., while we applied to F.C.C. rulemaking the "arbitrary and capricious" standard ..., it is hard to see in what respect we would have treated the question differently if we had been applying a "substantial evidence" test .... While we still have a feeling that there may be cases where an adjudicative determination not supported by substantial evidence ... would not be regarded as arbitrary and capricious, ... in the review of rules of general applicability made after notice and comment rulemaking, the two criteria do tend to converge.

Id. at 349-50 (citations and footnotes omitted). *See also* Friendly, "*Some Kind of Hearing*," 123 U. Penn. L. Rev. 1267, 1313-14 (1975).

In Industrial Union Dep't, AFL-CIO v. Hodgson, 499 F.2d 467 (D.C. Cir. 1974), the court stated that which of the two tests applied would not "affect the rigorousness of our review to the extent the Government seems to suppose, or that petitioners purport to fear." *Id.* at 473. In National Nutritional Foods Ass'n v. Weinberger, 512 F.2d 688 (2d Cir. 1975), a case arising under the Food, Drug, and Cosmetic Act, Judge Lumbard asserted outright that the two tests are identical: "In essence I think that when an agency engages in substantive rule-making, it abuses its discretion (or acts arbitrarily or capriciously) if its actions are not supported by substantial evidence." *Id.* at 705 (concurring opinion of Lumbard, J.).

(footnote continued)

the information before it and has acted rationally. And the fundamental rule under either test is that courts may not substitute their judgment for the Secretary's. *Consolo* v. *Federal Maritime Comm'n*, 383 U.S. 607, 619-21 (1966); *Universal Camera Corp.* v. *NLRB*, 340 U.S. 474, 491 (1950); [redacted], *Citizens to Preserve Overton Park* v. *Volpe*, 401 U.S. 402, 415-16 (1971).

In *Industrial Union Dep't*,[174] the court illustrated the application of these principles as follows:

> For example, in this case the evidence indicated that reliable data is not currently available with respect to the precisely predictable health effects of various levels of exposure to asbestos dust; nevertheless, the Secretary was obligated to establish some specific level as the

(footnote concluded)

The Conference Report on the 1977 Clear Air Act Amendments cites this trend, and *Associated Industries* in particular, with approval. H.R. REP. NO. 564, 95th Cong., 1st Sess. 178 (1977).

It has been suggested that the primary function of specifying the substantial evidence test with informal rulemaking may be to restrict the agency to a record. Scalia & Goodman, *Procedural Aspects of the Consumer Product Safety Act*, 20 U.C.L.A. L. Rev. 899, 935, n. 138 (1973). But even this distinction between the tests is elusive, since some recent statutes specifying the arbitrary or capricious test also provide for such a record. See § 307(d) of the Clean Air Act, 42 U.S.C. § 7607(d). Under either review test, such a record must reflect both the factual matters at issue and the principles, hypotheses, and policies by which the agency reasons to its decision.

Thus it may be time for this Court to re-examine the assumption, expressed in Abbott Laboratories v. Gardner, 387 U.S. 136, 143 (1967), that the tests really do define different depths of judicial scrutiny of agency decisions, at least in highly technical, largely legislative areas such as these.

[174] 499 F.2d 467 (D.C. Cir. 1974).

> maximum permissible exposure. After considering all the conflicting evidence, the Secretary explained his decision to adopt, over strong employer objection, a relatively low limit in terms of the severe health consequences which could result from over-exposure. Inasmuch as the protection of the health of employees is the overriding concern of [the Act], this choice is doubtless sound, but it rests in the final analysis on an essentially legislative policy judgment, rather than a factual determination, concerning the relative risks of underprotection as compared to overprotection.[175]

This is the conclusion the Fifth Circuit should have reached.

B. The Secretary Reasonably Determined That Quantitative Risk Assessment Techniques Are Not Sufficiently Reliable To Be A Basis For Decision

In this case, the Secretary determined that techniques for quantifying cancer risk cannot yet yield estimates that are sufficiently reliable to be a basis for setting the permissible level of exposure to benzene.[176] He concluded that the exercise could not "significantly clarify the ultimate decision.[177] He stated the essential uncertainties about how chemicals cause cancer which preclude reliable quantification. He stated the problems that preclude quantitative reliance on the epidemiological studies which identify benzene as a leukemogen. There were large

[175] *Id.* at 475.

[176] 43 Fed. Reg. 5940-41 (1978). In addition, the Secretary explicitly incorporated into the benzene preamble, *id.* at 5941, his detailed consideration of the same issue in setting the coke oven emissions standard, 41 Fed. Reg. 46,742, 46,750-51 (1976).

[177] [redacted] Fed. Reg. [redacted]
43 5941.

uncertainties about the exact doses to which employees studied had been exposed. It was likely that the studies had not recorded all the cases of leukemia caused by benzene in these employees, because the full latency period may not yet have run since exposure began, and because all exposed employees have not been located and examined. There could be no quantitative estimates based on animal studies even if these estimates could be made reliably, because benzene's carcinogenicity has not yet been adequately shown in an animal test. Whether benzene interacts with other chemicals and whether it causes other cancers less readily identified and traced to a source than leukemia could not be established. Also, any reliable quantitative estimate would have to take into account benzene's effects other than cancer, some of which can also be fatal, and about which there are many similar quantitative uncertainties.[178]

For these reasons, the Secretary rejected the back-of-the-envelope calculations offered by industry witnesses and declined to generate ones of his own.[179] This decision was reasoned and well-supported. Indeed, the Secretary could not have reached any other conclusion consistent with the Occupational Safety and Health Act's mandate to take preventive action on the basis of the best available evidence.

The Fifth Circuit opinion shows that it simply failed to grasp how uncertain and imprecise the quantitative risk estimates really are. The court appears to have been misled into concluding that such techniques could pinpoint the size of the danger, when in fact they cannot even

[178] 43 Fed. Reg. 5930-32, 5940-41.

[179] *Id.* at 5940-41.

provide assurance of being within several orders of magnitude of true risks.[180]

In any event, it is not the court's role to decide de novo whether the Secretary's conclusion was correct. The court can only overturn his rejection of quantitative risk

[180] American Petroleum Inst. v. OSHA, 581 F.2d 493, 503-05 (5th Cir. 1978). In a footnote, the court referred to two particular items. *Id.* at 504 n. 23. The court cited a quantitative risk assessment performed for benzene by a unit in the Environmental Protection Agency. But this early version of the EPA document lacked a passage present in the final draft, which explains some of the heroic assumptions that the authors made concerning the substantial uncertainties. This addition undercuts the undeserved confidence the court placed in its quantitative conclusions. See the final version, EPA Carcinogen Assessment Group, Final Report On Population Risk to Ambient Benzene Exposures (with cover memorandum dated January 10, 1979).

Moreover, while a unit at EPA produces such estimates for informational purposes, the EPA Administrator has not adopted the policy of relying on these estimates in determining standards or other regulations under any of the half dozen statutes for control of chemical hazards that he administers. Thus the lower court had no basis from EPA's actions to impugn the Secretary's judgment.

The court also cited the mere averment by an economic consultant to the agency to the effect that he could do cost-effectiveness analysis, which the court stated was "an analysis which would have included some kind of risk quantification." This statement, by one who is not expert in the complex scientific issues of cancer causation, was hardly a sound basis for the court's conclusion that reliable quantitative risk assessments can be performed.

Beyond these specifics, the court appears simply to have accepted the assurances of employer's witnesses, who ignored the massive uncertainties in the techniques. The lower court adopted the term "rough" to describe the estimates it required. *Id.* at 504. This choice of terms reflects its confusion on the power of these techniques. If the court actually believed that

(footnote continued)

assessment if it can properly conclude that, under the present state of knowledge and the policies of the Act, the Secretary was irrational. In fact, the court *conceded* the Secretary's determinations were rational.[181] Thus, the lower court's decision cannot stand.

(footnote concluded)
"rough" estimates can come usefully close to the true risk, then it simply failed to comprehend the irreducible uncertainties in these techniques. If the court understood that "rough" estimates really may be off by a factor of as much as 5,000,000 (see text accompanying note 68, *supra*), then the court's conclusion that they are a useful basis for decisions was simply without logical foundation. This use of the term "rough" distorts the English language to the point of squeezing all meaning out of the word.

[181] 581 F.2d at 503.

CONCLUSION

The lower court has substituted its judgment for that of Congress and the Secretary on the proper means to protect employees from cancer and other serious diseases caused by chemicals in the workplace. The court would impose on the Secretary quantitative decision-making requirements that Congress did not mandate, and that the Secretary reasonably rejected. The decision would preclude the Secretary from taking effective preventive measures until a speculative future time when science has solved the mysteries of carcinogenesis and policy-makers have devised adequate quantitative means of making basic societal decisions. With the knowledge that this day is remote, Congress envisioned, and the Secretary has practiced, a decision making process sensitive to the qualities of the best available data and to the reality that human lives and health are at stake. The lower court would undo this. For these reasons, this Court should reverse the decision below, and remand with instructions for a decision consistent with the Occupational Safety and Health Act as outlined here.

Respectfully submitted,

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1978

No. 78-911

INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
Petitioner,

v.

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No. 78-1036

RAY MARSHALL, SECRETARY OF LABOR,
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Respondents.

On Writs of Certiorari to the United States Court of Appeals for the Fifth Circuit

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BRIEF FOR THE INTERNATIONAL UNION, UNITED AUTOMOBILE, AEROSPACE AND AGRICULTURAL IMPLEMENT WORKERS OF AMERICA, UAW AS AMICUS CURIAE

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---

BRIEF FOR THE INTERNATIONAL UNION, UNITED AUTOMOBILE, AEROSPACE AND AGRICULTURAL IMPLEMENT WORKERS OF AMERICA, UAW AS AMICUS CURIAE

INTEREST OF AMICUS

The UAW is a labor organization which directly represents 1.5 million active workers in the United States and Canada. Approximately 7,600 of its members are employed by companies who are members of the Rubber Manufacturers Association, Inc., a respondent in this case. A significant number of those UAW members are exposed to benzene, the product which the Secretary of Labor proposed to regulate under 29 C.F.R. § 1910.1028. All of the UAW's United States members work in operations under state or national health standards which must achieve minimum levels of protection comparable to those health standards promulgated by the Occupational Safety and Health Administration, United States Department of Labor.

The UAW has a long history of devoting its attention to the health and safety concerns of its members, both as an important collective bargaining issue during major contract negotiations and continuously thereafter in the daily operation of the facilities where its members work. In all situations, the UAW is dedicated to the protection of the lives and bodies of workers.

We believe that unless this Court reverses the decision below, the administration of the Occupational Safety and Health Act of 1970 will be dealt a major blow. Some workers are likely to lose their lives or be seriously hurt if a cost-benefit analysis is deemed to be a requirement of the Secretary of Labor's health and safety standard setting procedure.

CONSENT OF THE PARTIES

This brief *amicus curiae* in support of the Petitioners is filed with the consent of all parties.

QUESTION PRESENTED

The Secretary of Labor has the authority to promulgate standards dealing with toxic materials and harmful physical agents pursuant to the Occupational Safety and Health Act of 1970. In promulgating a standard dealing with a known carcinogen, must the Secretary quantify and weigh the expected loss of human life or damage to human health against compliance costs before reducing atmospheric exposure to the lowest level feasible in order to assure no employee will suffer a material impairment of health or functional capacity?

STATEMENT OF THE CASE

This case concerns the Secretary of Labor's (the Secretary) effort to reduce the permissible level of benzene to which workers can be exposed. Benzene is a clear, flammable liquid which vaporizes easily under ordinary atmospheric conditions. It is produced by the petrochemical and petroleum refining industries and used in the manufacture of many products such as rubber. 43 Fed. Reg. 5918. Benzene has been a known toxin since 1900, and was first regulated by the State of Massachusetts Division of Occupational Hygiene in 1934. 43 Fed. Reg. 5918. It has long been known that benzene could cause acute circulatory problems or failure, as well as chronic non-malignant effects such as anemia and leukopenia, and thrombocytopenia.[1] Some of these problems are potentially fatal. On the basis of these facts, the American Conference of Industrial Hygenists (ACGIH) recom-

[1] Anemia is a decline in the red blood cell count causing a reduced supply of oxygen to the body. Leukopenia is a decline in the white blood cell count causing a hyperproprensity to recurrent infections. Thrombocytopenia is a decline in the platelet count causing impaired clotting of the blood. 43 Fed. Reg. 5921-22.

mended a benzene exposure level of 100 ppm in 1946. The ACGIH subsequently reduced the proposed exposure level to 35 ppm in 1948 and to 25 ppm in 1963. 43 Fed. Reg. 5918. In 1971, OSHA adopted the benzene in air exposure level of 10 ppm recommended by the American National Standards Institute as the national consensus standard under 29 C.F.R. § 1910.1000, Table Z-2.

In addition, some scientists have associated benzene with leukemia in humans since 1897. 43 Fed. Reg. 5925. Leukemia is a cancer of the white blood cells, from which there is little chance of permanent recovery. 43 Fed. Reg. 5925.

In 1974, the National Institute for Occupational Safety and Health (NIOSH)[2] submitted a criteria document to the Occupational Safety and Health Administration (OSHA) which noted that the "possibility that benzene can induce leukemia cannot be dismissed." 43 Fed. Reg. 5919. In August, 1976, NIOSH submitted another criteria document which noted an apparent link between exposure to benzene and leukemia. NIOSH recommended an exposure level of 1 ppm in air. 43 Fed. Reg. 5919. By April 15, 1977, the preliminary results of an epidemiological study by Dr. Infante of a Goodyear Tire and Rubber Company facility indicated exposure to benzene was related to a fivefold increased risk of dying of leukemia. 43 Fed. Reg. 5927.

Having been repeatedly prompted to lower the benzene exposure standard by NIOSH, the Assistant Secretary for the Occupational Safety and Health Administration issued an Emergency Temporary Standard for Occupational Exposure to Benzene (ETS), 42 Fed. Reg. 22516.[3] The ETS reduced permissble benzene levels in

[2] NIOSH was created by Congress in 1970 to conduct research in the field of occupational safety and health. 29 U.S.C. §§ 669, 671.

[3] The Secretary's basic authority for emergency temporary standards is found in 29 U.S.C. § 655(c).

air to 1 ppm. The standard never became effective because of a stay order issued by the Court of Appeals for the Fifth Circuit on May 20, 1977. *American Petroleum Institute* v. *OSHA*, No. 77-1516.

On May 27, 1977, OSHA published a proposed permanent standard for occupational exposure to benzene. 42 Fed. Reg. 27452. The proposed standard was to have reduced workplace exposure to benzene in air from 10 ppm to 1 ppm, exempted those work operations where the only exposure to benzene was from liquids containing one percent or less of benzene by volume, and established certain requirements for exposure monitoring, medical surveillance, methods of compliance, liability and record-keeping. Public hearings were held from July 19 through August 10, 1977, at which 95 witnesses appeared on behalf of employer associations, government agencies, public interest groups, unions and other interested persons. The witnesses generated a transcript over 3400 pages long and an exhibit list of over 1400 items.

On February 10, 1978, the Secretary promulgated a new permanent standard for occupational exposure to benzene to be codified as 29 C.F.R. § 1910.1028, 43 Fed. Reg. 5963-70, and accompanied by a statement of reasons 43 Fed. Reg. 5918-63. As originally published, the standard required employers to reduce exposure to benzene in air from 10 ppm to 1 ppm averaged over an eight-hour day; prohibited dermal contact with liquid benzene; required labeling of benzene containers, exposure monitoring, initial respiratory protection as well as engineering and work practice controls. The statement of reasons indicates the Secretary's basic goal was to reduce occupational exposure to benzene to the lowest level feasible. 43 Fed. Reg. 5918, 5932. OSHA subsequently amended the standard on June 27, 1978 which *inter alia* exempted work operations from coverage by the standard where the only exposure was to benzene contained in liquids

which were 0.5 percent benzene by volume. 43 Fed. Reg. 27962-71.

The standard was immediately challenged by various trade associations pursuant to 29 U.S.C. § 655(f), and the cases were consolidated in case No. 78-1253 by the Court of Appeals for the Fifth Circuit. The principal attacks on the standard focused on the reduction of the permissible exposure limit for benzene in air, the prohibition of dermal contact with liquids containing benzene, and the labeling requirements. The reviewing court specifically vacated the permissible exposure limit and the prohibition of dermal contact. The court also vacated the remainder of the standard as integrally related to the two provisions specifically vacated. *American Petroleum Institute* v. *Occupational Safety and Health Administration*, 581 F.2d 493 (5th Cir. 1978), *cert. granted*, Nos. 78-911 and 78-1036 (*API* v. *OSHA*).

ARGUMENT

The Lower Court's Injection Of Cost-Benefit Analysis Into The Act's Standard-Setting Process Is Grave Error.

Upon reviewing the Secretary's decision to reduce workplace exposure to benzene, a known carcinogen, the court below vacated the Secretary's standard on the ground that he failed to balance the industry compliance costs against the expected benefits of the new standard. *American Petroleum Institute* v. *Occupational Safety and Health Administration*, 581 F.2d 493 (5th Cir. 1978), *cert. granted*, Nos. 78-911 and 78-1036.

There are several aspects of the court's decision which are in error and require reversal. As an initial matter, the court ignored § 6(b)(5) of the Occupational Safety and Health Act of 1970, 29 U.S.C. § 655(b)(5), which sets forth the criteria the Secretary of Labor must observe

in promulgating standards for carcinogens. Instead, the court looked to one of the paragraphs in the definitional section of the Act, § 3(8), 29 U.S.C. § 652(8)[4] and held:

> The Act imposes on OSHA the obligation to enact only standards that are reasonably necessary or appropriate to provide safe or healthful workplaces. If a standard does not fit in this definition, it is not one that OSHA is authorized to enact. [581 F. 2d at 502].

The court then went on to hold that in order to determine that a standard is "reasonably necessary," the Secretary must

> determine whether the benefits expected from the standard bear a reasonable relationship to the costs imposed by the standard. [581 F. 2d at 503].

By commanding the Secretary to compare costs against benefits, the court committed two additional, grave mistakes. *First*, the court compels the Secretary to perform a cost-benefit analysis, though the concepts of risk quantification and benefit valuation are nowhere referred to or implied in the Act. *Second*, the court looks for support for this special balancing in the standard promulgation criteria set forth in the wholly different Consumer Products Safety Act, 15 U.S.C. § 2051 *et seq.* This totally inappropriate style of statutory construction yields results which are antithetical to Congress' basic purposes in enacting the Occupational Safety and Health Act of 1970 (OSH Act), 29 U.S.C. § 651 *et seq.*

---

[4] 29 U.S.C. § 652(8) provides:

> The term 'occupational safety and health standard' means a standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment.

A. *The Act Does Not Authorize The Secretary To Weigh Lives Against Costs When Dealing With A Carcinogen.*

The Secretary has a special mandate under the OSH Act to regulate exposure to carcinogens. Section 6(b)(5) provides in part:

> The Secretary, in promulgating standards dealing with *toxic materials or harmful physical agents* under this subsection, shall set the standard which *most adequately assures*, to the extent feasible, on the basis of the best *available* evidence, *that no employee will suffer material impairment of health or functional capacity* even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. [29 U.S.C. § 655(b)(5), (emphasis added)].

Congress, through this unusually imperative mandate, informed the Secretary that worker lives are of paramount importance. When regulating a carcinogen, he must establish some specific level of maximum permissble exposure, 29 U.S.C. § 655(b)(5),[5] even where the experts cannot identify a safe level of exposure to the carcinogen, *Industrial Union Department, AFL-CIO* v. *Hodgson*, 499 F.2d 467, 475 (D.C. Cir. 1974). "[I]t remains the duty of the Secretary to act to protect the workingman, and to act even in circumstances where existing methodology or research is deficient." *Society of Plastics Industries* v. *Occupational Safety and Health Administration*, 509 F.2d 1301, 1308 (2d. Cir. 1975), *cert. den.*, 421 U.S. 992 (1975).

It is also evident from the language of § 6(b)(5) that the Secretary is directed to reduce exposure to a carcinogen to the *lowest* level feasible since the level he must

[5] Section 6(b)(5) also provides in part:

> Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired. [29 U.S.C. § 655(b)(5)].

choose is that which "most adequately assures . . . that no employee will suffer material impairment of health or functional capacity." 29 U.S.C. § 655(b)(5).[6] These words do not authorize utilitarian balancing of costs and benefits by the Secretary. Such balancing would do great violence to the deep concern felt by Congress over the subject of preventable harm to workers.[7]

The lower court's decision violates not only the clear meaning of § 6(b)(5), but the Act's central purpose, as well.[8] By requiring the Secretary to quantify risks and benefits prior to promulgating a standard, the court effectively enjoins OSHA from regulating a carcinogen where there is no known safe level of exposure.[9] It is

[6] The Court below did not challenge the feasibility of the benzene standard. 581 F.2d 493.

[7] As the House Committee on Education and Labor said when it reported favorably on a substantially similar version of the bill that was ultimately passed by both houses:

> As a nation, we simply have not faced up to the truth; our men, women and children are being killed needlessly; they are being maimed, injured, disabled and infected on the job by largely preventable injuries and diseases.
>
> * * * *
>
> Modern logic will not permit the deliberate condoning of death, disease or injury when the causes are identifiable or preventable. . . . The well-being of every American working man and woman is an essential human right which we can no longer deny. [House Committee on Education and Labor, H.R. Rep. No. 91-291, 91st Cong. 2d Sess. 35 (1970); *reprinted in* Senate Committee on Labor and Public Welfare, 91st Cong. 2d Sess., *Legislative History of the Occupational Safety and Health Act of 1970* at 865 (*Leg. Hist.* at 865)].

[8] The Congress declares it to be its purpose and policy, . . . to assure so far as possible every working man and woman in the nation safe and healthful working conditions and to preserve our human resources . . . [29 U.S.C. § 651(b)].

[9] Were the Secretary able accurately to quantify the risk to health or functional capacity at each level of benzene exopsure, he would have to know the various degrees of safety attached to various levels of exposure.

clear, however, that Congress recognized that a safe level of exposure might not exist. House Committee on Education and Labor, H.R. Rep. 91-1291, 91st Cong., 2d Sess. 15 (1970); *reprinted in* Senate Committee on Labor and Public Welfare, 91st Cong., 2d Sess., *Legisiative History of the Occupational Safety and Health Act of 1970* at 845 (*Leg. Hist.*). Congress also recognized that scientific developments had only recently demonstrated any kind of relationship between various industrial substances and processes and certain chronic diseases and cancer. Senate Committee on Labor and Public Welfare, S. Rep. 91-1282, 91st Cong., 2d Sess. 2 (1970); *Leg. Hist.* at 142. However, Congress did not intend the Secretary to be "paralyzed by debate surrounding diverse medical opinions," House Committee on Education and Labor, H.R. Rep. 91-1291, 91st Cong., 2d Sess. 18 (1970); *Leg. Hist.* at 848, but directed him to set a standard on the basis of the "best available evidence." 29 U.S.C. § 655(b)(5). The court below adopted just the opposite interpretation of § 6(b)(5):

> By requiring the consideration of such kinds of information, Congress provided that OSHA regulate on the basis of knowledge rather than on the unknown. (Citing as contrary authority *SPI* v. *OSHA*, 509 F. 2d at 1308.) [*API* v. *OSHA*, 581 F. 2d at 504].

Based on that interpretation, the Court of Appeals commanded OSHA to wait until the risks are quantifiable before promulgating a benzene standard.

The court's insistence on cost-benefit balancing not only *delays* the setting of a benzene standard, but also ensures that the standard, if finally set, will be unfaithful to the paramount priority § 6(b)(5) gives human life. The usual mathematical method by which costs and benefits are comparable is through performance of a traditional cost-benefit analysis. A cost-benefit analysis in the area

of life or health preserving measures typically entails not only attaching monetary figures to the cost of a measure, but also the dollar valuation of benefits.[10] In order to attach a dollar value to a life saved or health preserved by a measure, the life itself must be valued. Yet the very step of valuing a life in dollar terms and balancing it against the cost of workplace safety measures *assumes* the life is not worth the cost to preserve it if the cost figure is greater than the life value figure. That assumption about the value of life is contrary to the Secretary's statutory mandate in § 6(b)(5).[11]

Even under the so-called "cost-effectiveness" approach as proposed by some witnesses during the informal hearings, the court would be asking OSHA to engage in tradeoffs or balancing. *E.g.*, Dr. Zeckhauser, Tr. 2142-2143. Those same witnesses go so far as to suggest OSHA should maximize benefits as they relate to the total costs borne by the consumer, Dr. Zeckhauser, Tr. 2158, or engage in relative acceptible risk analysis in light of the costs of preventing disease. Dr. Wilson, Ex. 149B at 23-27.

The balancing those witnesses and the court below seek was completed by Congress in 1970. That balancing was embodied in the statute in the concept of feasibility.[12] As

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[10] *See*, J.P. Acton, *Measuring the Monetary Value of Lifesaving Programs*, 40 JOURNAL OF LAW & CONTEMP. PROB. 46 (Aut. 1976).

[11] We do not argue that the express cost-benefit analysis required by Judge Clark might not be appropriate with regard to other agencies and other statutes. Rather, the UAW contends that such analysis is inappropriate with respect to the Occupational Health and Safety Administration's standard setting functions.

[12] Sen. Javits added the term "feasible" to S. 2193 because "the Daniels Bill . . . might be interpreted to require absolute health and safety in all cases . . . ." Senate Committee on Labor and Public Welfare, S. Rep. No. 91-1282, 91st Cong. 2d Sess. 5; *Leg. Hist.* at 197 (Individual Views of Mr. Javits).

long as the facts support a feasibility determination,[13] Congress has decreed that the balance between preserving the lives of working people and the cost thereof has been properly made.[14] It is not the function of the courts to supplant Congress in its role of policy maker, *Tennessee Valley Authority* v. *Hill*, —— U.S. ——, 98 S. Ct. 2279, 57 L. Ed. 2d 91 (1978), regardless of how absurd the result may seem to the challengers, *Director, Worker's Compensation Programs* v. *Rasmussen*, —— U.S. ——, 99 S. Ct. 903, 913, 59 L. Ed. 2d 122, 135 (1979) (unanimous decision).

> The fundamental policy questions appropriately resolved in Congress . . . are *not* subject to reexamination in the federal courts under the guise of judicial review of agency action. [*Vermont Yankee Nuclear Power Corporation* v. *Natural Resources Defense Council*, 435 U.S. 519, 558 (1978) (emphasis original)].

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[13] The concept of feasibility has been bifurcated to cover technological feasibility, *SPI* v. *OSHA*, 509 F.2d at 1308-1310, as well as economic feasibility, *American Federation of Labor* v. *Brennan*, 530 F.2d 109, 120-123 (3rd Cir. 1975); *American Iron & Steel Institute* v. *Occupational Safety and Health Administration*, 577 F.2d 826, 832-835 (3rd Cir. 1978), App. Pend. Nos. 78-918, 78-919. A standard is not economically feasible if it creates massive dislocation for an industry, *AISI* v. *OSHA*, 577 F.2d at 836; *AFL* v. *Brennan*, 530 F.2d at 123. *See also, IUD* v. *Hodgson* indicating any given employer may be forced out of business by a standard which is nevertheless economically feasible. 499 F.2d at 478.

[14] *Note*, there currently exists a dispute between the Circuit Courts of Appeals as to whether the concept of *feasibility* as applied to a single employer through enforcement proceedings must involve some form of cost-benefit or cost-effective analysis. *Compare, Southern Colorado Prestress Co.* v. *Occupational Safety and Health Review Commission*, 586 F.2d 1342 (10th Cir. 1978) with *RMI Co.* v. *Secretary of Labor*, —— F.2d ——, 1979 OSHD ¶ 23,386 (6th Cir. 1979); and *Turner Co., Div. of Olin Corporation* v. *Secretary of Labor*, 561 F.2d 82 (7th Cir. 1977).

B. *The Lower Court's Sole Justification For Reading A Cost-Benefit Requirement Into The Act Is Its Interpretation Of A Different Statute.*

The Court of Appeals sought to justify its injection of a cost-benefit requirement into the OSH Act by seizing upon the words "reasonably necessary" in the definitional section, § 3(8), and ignoring the standard setting criteria of § 6(b)(5). It then read into those words the same meaning it assigned them in its decision in *Aqua Slide* v. *Consumer Product Safety Commission*, 569 F.2d 831 (5th Cir. 1978), *construing the Consumer Product Safety Act*, 15 U.S.C. § 2051, *et seq.*[15] In so doing, the lower court lost sight of the fact that in the OSH Act it was interpreting a unique statute and not creating its own general regulatory policy. The court said:

> [w]e decline to construe the precisely similar requirements of these two Acts differently . . . [581 F. 2d at 502],

even though the requirements are not similar at all. Not only do the words "reasonably necessary or appropriate" not appear in the definitional section of the CPSA,[16] but

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[15] *E.g.*, § 7(a), CPSA provides:

> A consumer product safety standard shall consist of one or more of any of the following types of requirements.
>
> * * * *

Also, § 9(c)(2), CPSA provides:

> The Commission shall not promulgate a consumer product safety rule unless it finds and includes such finding in the rule—(a) That the rule (including its effective date) is reasonably necessary to eliminate or reduce an unreasonable risk to injury associated with such product. [15 U.S.C. § 2058(c)(2)].

[16] Section 3(a)(7) provides:

> The term 'consumer product safety rule' means a consumer product safety standard described in section 2056(a) of this title, or a rule under this chapter declaring a consumer product a banned hazardous product. [15 U.S.C. § 2052(a)(2)].

the two acts have very different approaches to the promulgation of standards, and their basic philosophies are not compatible.

Both statutes are governed by the substantial evidence test, according to their express terms.[17] However, under the express language of the CPSA findings which must be supported by substantial evidence include:

> appropriate findings for inclusion in such rule with respect to—
>
> (A) The degree and nature of the risk of injury the rule is designed to eliminate or reduce; [15 U.S.C. § 2058(c)(1)(A)].

Such findings were obviously what the court below had in mind when it held that, under the OSH Act the Secretary must quantify the risks before acting. 581 F.2d at 504-505. Yet, the OSH Act makes no such reference to risk analysis. Nor can one legitimately be implied.

The CPSA is permeated by the concept of "unreasonable risk" in the tort case. *Aqua Slide* v. *CPSC*, 569 F.2d at 839; *Forester* v. *Consumer Product Safety Commission*, 559 F.2d 774 (D.C. Cir. 1977).[18] In the context of tort law, the value of a product to society is weighed against the harm to those who use and are injured by it.[19] But in the OSH Act, Congress left no room for

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[17] *Compare*, § 11(c), CPSA, 15 U.S.C. § 2060(c) and § 6(f), OSHA, 29 U.S.C. § 655(f).

[18] *See*, Congressional findings and declaration of purpose, § 2, CPSA, 15 U.S.C. § 2051.

[19] The requirement that the risk be 'unreasonable' necessarily involves a balancing test like that familiar in tort law: The regulation may issue if the severity of the injury offsets the harm the regulation itself imposes upon manufacturers and consumers, (footnote omitted) [*Forester* v. *CPSC*, 557 F.2d at 789].

special balancing outside the concept of feasibility.[20] In addition to what is said in § 6(b)(5), Congress declared it to be its purpose in enacting the OSH Act "to assure *so far as possible* every working man and woman in the nation safe and healthful working conditions." 29 U.S.C. § 651(b) (emphasis added).

In enacting CPSA, Congress' concern was not with banning all product hazards to the extent feasible, but with protecting "the public against *unreasonable risks* of injury associated consumer products." § 2(b)(1), CPSA, 15 U.S.C. 2051(b)(1) (emphasis added). The Congress' concerns and concepts were those utilized in tort law. *Forester* v. *CPSC*, 559 F.2d at 789 n.1 (and accompanying text). The more careful, generalized balancing contemplated in tort law and required of the Commission under the CPSA is not relevant to the quite different matter of preserving worker lives and health. It was therefore totally inappropriate for the court first to conclude the Congressional purpose embodied in the CPSA is the same as that in the OSH Act, and then to hold that since the CPSA requires a cost-benefit analysis, the OSH Act must too!

Although giving the words "reasonably necessary" in § 3(8) precedence over § 6(b)(5) and interpreting those words to say what they mean in a different statute is error, § 3(8) must nevertheless be construed. In light of the detailed directions given the Secretary in § 6(b)(5), the words in § 3(8) should not be read to establish a new, separate factual test which the Secretary must meet. Instead, the words should be read to confirm the requirement that any choices the Secretary makes with regard to standards must be reasonable. Such a reading preserves the distinction between factfinding and policymaking as appreciated by the courts which have reviewed

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[20] *See*, discussion above at p. 11-12.

occupational safety and health standards in light of the Act's legislative history.[21] It also avoids the conclusions that the Secretary is not empowered to make policy choices in the absence of hard facts,[22] or that he must make findings not mandated by the language of § 6(b)(5).

---

[21] The standard of review § 6(f), OSH Act, 29 U.S.C. § 665(f) was added to S. 2193 at Conference as part of a compromise to some House fears that the Secretary of Labor would become too powerful. *See, e.g.*, House Committee on Education and Labor, H.R. Rep. 91-1291, 91st Cong. 2d Sess., Report on Occupational Safety and Health Act, Minority Views and Additional Minority Views, 53-55 (1970); *Leg. Hist.* at 883-885; and Rep. Anderson, *Leg. Hist.* at 1070, remarks in support of the Steiger-Sikes substitution (Nov. 23, 1970). The addition of the passage:

> The determination of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole, [29 U.S.C. § 655(f)],

was intended to insure factual findings would be based on probative evidence not just views and arguments. *See, Leg. Hist.* at 884. This created some ambiguity as to the scope of review. All of the Courts of Appeals have concluded that they must distinguish between legislative-like decisions and factual findings. In *IUD* v. *Hodgson*, 499 F.2d 467, the court upheld the Secretary's asbestos standard pursuant to 29 U.S.C. § 655(f) saying that provision required the court to distinguish between facts needing a basis in substantial evidence and policies which were required to meet the arbitrary and capricious test. 499 F.2d at 474-476. Denying petitions to review an ethyleneimine standard under 29 U.S.C. 655(f), former Justice Clark distinguished between substantial evidence review of factual matters subject to evidentiary development and review of policy decisions through the legal criteria governing the Secretary's consideration of relevant factors. *Synthetic Organic Chemical Manufacturers* v. *Brennan*, 503 F.2d 1155, 1159-1160 (3rd Cir. 1974), *cert. den.*, 402 U.S. 973 (1975). *See also, SPI* v. *OSHA*, 509 F.2d 1301, in which the Second Circuit upheld the vinyl chloride standard. It distinguished between traditonal facts and "ultimate facts . . ." where "though the factual finger points it does not conclude." Since the latter situation existed, the Secretary's choice to err on the side of worker health was found consistent with his duty under the act and was therefore upheld. 509 F.2d at 1308.

[22] *See*, discussion above, p. 9-10.

CONCLUSION

For the reasons discussed above, the decision of the Court of Appeals for the Fifth Circuit should be reversed and the standard upheld.

Respectfully submitted,

JOHN A. FILLION
General Counsel

CLAUDE D. MONTGOMERY
Assistant General Counsel
8000 E. Jefferson Avenue
Detroit, Michigan 48214

Counsel for International Union, UAW

Dated: May 15, 1979

IN THE

Supreme Court of the United States

OCTOBER TERM, 1978

Supreme Court, U. S.
FILED
JUL 30 1979
MICHAEL RODAK, JR., CLE

Nos. 78-911 and 78-1036

INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*,
Respondents.

RAY MARSHALL, SECRETARY OF LABOR,
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*,
Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Fifth Circuit

MOTION FOR LEAVE TO FILE BRIEF AS AMICI CURIAE, AND BRIEF AS AMICI CURIAE, OF

JOSEPH CIMINO, M.D., M.P.H., M.I.H.
HARRY B. DEMOPOULOS, M.D.
DAVID KRITCHEVSKY, Ph.D.
ELIZABETH C. MILLER, Ph.D.
JAMES MILLER, Ph.D.
PAUL M. NEWBERNE, Ph.D.
STEVE TANNENBAUM, Ph.D.
BERNARD M. WAGNER, M.D.
VERNON R. YOUNG, Ph.D.

AS INDIVIDUAL MEDICAL SCIENTISTS RELATING TO THE SCIENTIFIC (DERMAL CONTACT) ISSUE

JAMES R. RICHARDS
1101 17th Street, N.W.
Washington, D.C. 20036
Counsel

July 30, 1979

PRESS OF BYRON S. ADAMS PRINTING, INC., WASHINGTON, D. C.

IN THE

Supreme Court of the United States

OCTOBER TERM, 1978

Nos. 78-911 and 78-1036

INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*,
Respondents.

RAY MARSHALL, SECRETARY OF LABOR,
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*,
Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Fifth Circuit

---

MOTION FOR LEAVE TO FILE BRIEF AS AMICI CURIAE OF JOSEPH CIMINO, M.D., M.P.H., M.I.H., HARRY B. DEMOPOULOS, M.D., DAVID KRITCHEVSKY, Ph.D., ELIZABETH C. MILLER, Ph.D., JAMES MILLER, Ph.D., PAUL M. NEWBERNE, Ph.D., STEVE TANNENBAUM, Ph.D., BERNARD M. WAGNER, M.D., AND VERNON R. YOUNG, Ph.D., AS INDIVIDUAL MEDICAL SCIENTISTS

Drs. Joseph Cimino, Harry B. Demopoulos, David Kritchevsky, Elizabeth C. Miller, James Miller, Paul

M. Newberne, Steve Tannenbaum, Bernard M. Wagner, and Vernon R. Young (hereinafter the "individual scientists") hereby respectfully move, pursuant to Rule 42 of the Court, for leave to file the attached brief as *amici curiae* in the above-captioned consolidated cases.

The Solicitor General, on behalf of petitioner in No. 78-1036, has consented to the filing of the attached brief.[1] Similarly, counsel for all respondents in the consolidated cases have granted consent.[2] However, by a letter dated July 13, 1979, counsel for the Industrial Union Department, AFL-CIO ("IUD"), petitioner in No. 78-911, refused consent to the filing of a brief *amici curiae* by the individual scientists.[3]

In support of this motion, the individual scientists state the following:

1. The individual scientists are engaged in scientific research and other academic pursuits at teaching universities. Their qualifications are briefly summarized in note 1 of the attached brief.

2. The individual scientists have no pecuniary interest in this litigation. Among their various activities, they are engaged in conducting research and experimental programs which sometimes are, and more often should be, utilized by the United States Government in making health regulatory decisions. As academic scientists, they have a special perspective on the manner in

[1] The Solicitor General's consent is attached as Appendix A to this motion *infra*, at vi .

[2] Respondents' consents are attached as Appendices B-I to this motion *infra*, at vii-xiv.

[3] The IUD's refusal is attached as Appendix J to this motion *infra*, at xv-xvi.

which the scientific community can contribute to and strengthen the regulatory process by providing scientific data on questions as to which the Occupational Safety and Health Administration ("OSHA") and other agencies require prompt, reliable answers. If the government would determine to act on the basis of research and scientific data, this circumstance would motivate the scientific community to generate the required data. In particular, the individual scientists believe that presentation of their views may materially aid this Court's resolution of the second (dermal contact) issue in these cases, relating to the proper scientific basis required to support OSHA standards. None of the parties has the special perspective leading to analysis of the second issue from a scientific viewpoint. And it is counsel's understanding that none of the other corporations and organizations filing briefs *amicus curiae* are expected to address the second issue.

3. The individual scientists are filing this motion, and request leave to file the attached brief *amici curiae*, as individuals, and not as members of any organization, academic institution or other group. While the individual scientists believe their views have substantial support in the scientific community, the views expressed in the attached brief are solely those of the named individuals.

4. In refusing consent to the filing of a brief *amici curiae* by the individual scientists, counsel for the IUD noted that such consent had been requested on behalf of individual physicians and scientists, but stated that "it does not appear that your clients represent the entire 'scientific community' or even that they represent any particular scientific organization." App. I *infra*, at xvi. As stated above, the individual scientists seek

to present only their own views, and do not in any way purport to represent the views of any other person or group. A group of scientists (or other persons) with a common interest and perspective should be welcome to express their views to this Court in their individual capacities, without being required to locate or even create an organization through which they must state their position. To our knowledge, there is no requirement in this Court's rules or otherwise that only corporations or formal organizations can file briefs *amicus curiae* with the Court, and no such requirement should be imposed.

5. The IUD's other stated basis for refusing its consent was that the "IUD does not believe that the views of individual scientists as to what the record reflects are a proper subject for an *amicus* brief in the Supreme Court." *Id.* Whether or not the IUD is correct on this point is irrelevant to the present motion. The attached brief does not discuss the record evidence in these cases.

6. The attached brief *amici curiae* is addressed solely to the second (dermal contact) issue in these cases. As stated above, it is understood that none of the other organizations which have received the consent of all parties to file briefs *amicus curiae* in the cases will address the second issue. The IUD, the only party which refused consent to the filing of the attached brief, stated only the first issue in these cases in both its petition for certiorari and its brief on the merits, and the IUD's brief on the merits does not discuss the second (dermal contact) issue at all.

7. The attached brief is being filed within the time prescribed by Rule 42.

WHEREFORE, the individual scientists named above respectfully request that leave to file the attached Brief as Amici Curiae be granted.

Respectfully submitted,

JAMES R. RICHARDS
1101 17th Street, N.W.
Washington, D.C. 20036
Counsel

APPENDIX A

OFFICE OF THE SOLICITOR GENERAL
Washington, D.C. 20530

July 11, 1979

James R. Richards, Esq.
1101 17th Street, N.W.
Suite 810
Washington, D.C. 20036

Re: Industrial Union Department, AFL-CIO v. American Petroleum Institute, et al., No. 78-911; Ray Marshall, Secretary of Labor v. American Petroleum Institute, et al., No. 78-1036

Dear Mr. Richards:

On behalf of the federal parties, I consent to your filing a brief *amicus curiae* in these cases.

Sincerely yours,

/s/ WADE H. MCCREE, JR.
Wade H. McCree, Jr.
Solicitor General

APPENDIX B

CLEARY, GOTTLIEB, STEEN & HAMILTON
1250 Connecticut Avenue, N.W.
Washington, D.C. 20036

July 11, 1979

James R. Richards, Esq.
1101 17th Street, N.W.
Suite 810
Washington, D.C. 20036

Re: *Industrial Union Department, AFL-CIO* v. *American Petroleum Institute, et al.*, No. 78-911; *Ray Marshall, Secretary of Labor* v. *American Petroleum Institute, et al.*, No. 78-1036.

Dear Mr. Richards:

Our clients, the Rubber Manufacturers Association, *et al.*, consent to the filing of a brief *amicus curiae* by Dr. Harry B. Demopoulos and other individual physicians and scientists in the above-styled consolidated cases.

Very truly yours,

/s/ CHARLES F. LETTOW
Charles F. Lettow

cc: Counsel for all parties

APPENDIX C

KIRKLAND & ELLIS

1776 K Street, N.W.
Washington, D.C. 20006

July 12, 1979

James R. Richards, Esq.
Capital Legal Foundation
1101 17th Street, N.W.
Suite 810
Washington, D.C. 20036

Re: IUD v. API & Marshall v. API, Nos. 78-911 & 78-1036

Dear Mr. Richards:

On behalf of the American Petroleum Institute, *et al.*, we consent to the filing of a brief *amicus curiae* by Dr. Harry B. Demopoulos in the above-styled case.

Sincerely,

/s/ EDWARD W. WARREN
Edward W. Warren

EWW: ma
cc: All Counsel

APPENDIX D

WILMER, CUTLER & PICKERING

1666 K Street, N.W.
Washington, D.C. 20006

July 11, 1979

James R. Richards, Esq.
Attorney at Law
1101 17th Street, N.W.
Suite 810
Washington, D.C. 20036

Re: *Industrial Union Department, AFL-CIO* v. *API*, No. 78-911; *Marshall* v. *API*, No. 78-1036

Dear Mr. Richards:

On behalf of the American Iron and Steel Institute, we hereby consent to the filing, on behalf of Dr. Harry B. Demopoulos, *et al.*, of a brief *amicus curiae* in the above-captioned actions.

Very truly yours,

/s/ NEIL JAY KING
Neil Jay King

cc: All Counsel

APPENDIX E

E. I. DUPONT DE NEMOURS & COMPANY
INCORPORATED

Wilmington, Delaware 19898

July 12, 1979

Legal Department

James R. Richards, Esq.
Attorney at Law
1101 17th Street, N.W.
Suite 810
Washington, D.C. 20036

Re: *Industrial Union Department, AFL-CIO* v. *API*, No. 78-911; *Marshall* v. *API*, No. 78-1036

Dear Mr. Richards:

Please be advised that on behalf of the Du Pont Company, we consent to your filing a brief *amicus curiae* in the above-captioned cases as counsel to Dr. Harry B. Demopoulos, et al.

Very truly yours,

/s/ JOHN F. DICKEY
John F. Dickey
Attorney
Environment Division

JFD: kes

APPENDIX F

INDEPENDENT PETROLEUM ASSOCIATION OF AMERICA

1101 Sixteenth St., N.W.
Washington, D.C. 20036

July 11, 1979

Mr. James R. Richards
Attorney At Law
1101 17th Street, N.W.
Suite 810
Washington, D.C.

Re: *Industrial Union Department, AFL-CIO* v. *API*, No. 78-911; *Marshall* v. *API*, No. 78-1036

Dear Mr. Richards:

The Independent Petroleum Association of America hereby consents to the filing of a brief *amicus curiae* by Dr. Harry B. Demopoulos, et al., in the above-referenced case.

Sincerely,

/s/ HAROLD B. SCOGGINS, JR.
Harold B. Scoggins, Jr.

HBS: mk
cc: All Counsel

APPENDIX G

SELLERS, CONNER & CUNEO

Attorneys and Counselors
1625 K Street, Northwest
Washington, D.C. 20006

July 12, 1979

James R. Richards, Esq.
Attorney at Law
Suite 810
1101 Seventeenth Street, N.W.
Washington, D.C. 20036

Re: *IUD, AFL-CIO* v. *API, et al.*, No. 78-911
Marshall v. *API, et al.*, No. 78-1036

Dear Mr. Richards:

On behalf of our client, Chemical Specialties Manufacturers Association, we hereby consent to the filing of a brief *amicus curiae* by Dr. Harry B. Demopoulos, et al., in the above-captioned actions.

Sincerely,

/s/ ROBERT L. ACKERLY
Robert L. Ackerly

rla/bcs
cc: Counsel for all parties

APPENDIX H

WILMER, CUTLER & PICKERING

1666 K Street, N.W.
Washington, D.C. 20006

July 16, 1979

James R. Richards, Esq.
Attorney at Law
1101 17th Street, N.W.
Suite 810
Washington, D.C. 20036

Re: *Industrial Union Department, AFL-CIO* v. *API*, No. 78-911; *Marshall* v. *API*, No. 78-1036

Dear Mr. Richards:

In reply to your letter of July 6, 1979, concerning the above-referenced cases, I advise you that respondent Manufacturing Chemists Association consents to the filing of a brief *amicus curiae* by Dr. Harry B. Demopoulos and other individual physicians and scientists, including Dr. Joseph Cumino and Professor Benjamin Van Duren.

For your information, the Manufacturing Chemists Association has recently changed its name to the Chemical Manufacturers Association.

Sincerely yours,

/s/ JOHN H. PICKERING
John H. Pickering

cc: All Parties

APPENDIX I

PENNIE & EDMONDS

Counsellors at Law
330 Madison Avenue
New York, N.Y. 10017

July 11, 1979

James R. Richards, Esq.
1101 17th Street, N.W.
Suite 810
Washington, D.C. 20036

Re: IUD v. API & Marshall v. API, Nos. 78-911 and 78-1038

Dear Mr. Richards:

On behalf of the Republic Steel Corporation, we consent to the filing of a brief *amicus curiae* by Dr. Harry B. Demopoulos et al. in the above-styled case.

Very truly yours,

/s/ FRANK E. MORRIS
Frank E. Morris

cc: All Counsel

APPENDIX J

BREDHOFF, GOTTESMAN, COHEN & WEINBERG

Attorneys and Counselors
1000 Connecticut Avenue, N.W.
Washington, D.C. 20036

July 13, 1979

James R. Richards, Esq.
1101 17th Street, N.W.
Suite 810
Washington, D.C. 20036

Re: Industrial Union Department v. API, U.S. S.Ct. No. 78-911; Marshall v. API, U.S. S.Ct. No. 78-1036

Dear Mr. Richards:

This is to advise that the Industrial Union Department, AFL-CIO ("IUD") does not consent to your request to file a brief *amicus curiae* in the above-captioned case on behalf of "Dr. Harry B. Demopoulos and other individual physicians and scientists, including Dr. Joseph Cumino and Professor Benjamin Van Duren."

As you are undoubtedly aware, IUD has consented to the filing of *amicus* briefs in this case by several organizations, including the Capital Legal Foundation; and IUD would not ordinarily refuse such a request. However, having discussed with you the nature of your clients' claimed interest in this case, we have decided that your request should properly be refused.

Although your letter of July 6, 1979 requesting IUD's consent states that "the issues in these cases present questions of widespread interest in the scientific community," it does not appear that your clients represent the entire "scientific community," or even that they represent any particular scientific organization. Equally important, my understanding is that your clients merely have an academic interest in the manner in which certain scientific data in the record was interpreted by the Occupational Safety and Health Administration. While that might be a proper subject for testimony before the agency, IUD does not believe that the views of individual scientists as to what the record reflects are a proper subject for an *amicus* brief in the Supreme Court.

If I have in any way misunderstood the nature of your clients' interest in this case, do not hesitate to provide me with any additional information which you believe to be relevant to your clients' request.

Yours truly,

/s/ JEREMIAH A. COLLINS
Jeremiah A. Collins

cc: all counsel of record

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1978

Nos. 78-911 and 78-1036

INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*,
Respondents.

RAY MARSHALL, SECRETARY OF LABOR,
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*,
Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Fifth Circuit

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BRIEF AS AMICI CURIAE
OF

JOSEPH CIMINO, M.D., M.P.H., M.I.H.
HARRY B. DEMOPOULOS, M.D.
DAVID KRITCHEVSKY, Ph.D.
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BERNARD M. WAGNER, M.D.
VERNON R. YOUNG, Ph.D.

AS INDIVIDUAL MEDICAL SCIENTISTS
RELATING TO THE SCIENTIFIC (DERMAL CONTACT) ISSUE

INTEREST OF THE AMICI

The individual academic scientists [1] who have joined in this brief as "scientist-citizens" believe that this case presents issues which are of critical and lasting

[1] The qualifications of the university scientists are briefly summarized below. Further details regarding titles of published papers, and sources of research funding are available and will be furnished to the Court upon request.

Joseph Cimino, M.D., M.P.H., Masters in Industrial Health, Harvard University. President of New York Medical College, Valhalla, New York; former Commissioner of Health of New York City, 1971-1974.

Harry B. Demopoulos, M.D. Associate Professor of Pathology, New York University Medical Center, New York, New York; former Director of Cancer Center Planning, New York University Medical Center, 1973-1975.

David Kritchevsky, Ph.D. Associate Director, Wistar Institute, University of Pennsylvania, Philadelphia, Pennsylvania.

Elizabeth C. Miller, Ph.D. Professor of Oncology and Associate Director of the McArdle Laboratory for Cancer Research, Comprehensive Cancer Center, University of Wisconsin, Madison, Wisconsin.

James Miller, Ph.D. Professor of Oncology and Associate Director of the McArdle Laboratory for Cancer Research, Comprehensive Cancer Center, University of Wisconsin, Madison, Wisconsin.

Paul M. Newberne, Ph.D. Professor of Nutritional Pathology, Massachusetts Institute of Technology, Cambridge, Massachusetts, member of the National Academy of Sciences Panel on Saccharin and Cyclamates.

Steve Tannenbaum, Ph.D. Professor of Food Chemistry, Massachusetts Institute of Technology, Cambridge, Massachusetts.

Bernard M. Wagner, M.D. Professor of Pathology, Columbia University College of Physicians and Surgeons, Comprehensive Cancer Center, New York, New York; Editor of *Human Pathology* and Associate Editor of the *Journal of Environmental Pathology and Toxicology*.

Vernon R. Young, Ph.D. Professor of Nutritional Biochemistry, Massachusetts Institute of Technology, Cambridge, Massachusetts.

interest to the role of science in relation to the regulatory process. This Court's decision will undoubtedly influence the degree to which the Occupational Safety and Health Administration ("OSHA") utilizes science in developing its standards.

The *scientific validity* of regulatory standards represents an important long-term challenge facing a technologically advanced economy such as ours. The potentially dangerous chemical/physical processes which our society has come to rely on more and more require regulations that are arrived at by the *best science available*, and not through guesswork, which by its nature is likely to be incorrect and costly in terms of lives, health and/or economic viability.

The purpose of the academic scientists in filing this brief is to offer the Court some insight into the ways in which studies by the scientific community in the United States and in other countries can contribute to and *strengthen* the regulatory process via short-term (2-4 month) research, on questions where OSHA and other regulatory agencies require rapid, assured answers. This nation has an extensive, and largely federally funded, academic research establishment which has not been sufficiently utilized to assist OSHA in its difficult regulatory decisions.

The *amici* have no pecuniary interest in the case, but wish to bring to the Court's attention the views of some of the academic scientists [2] on how scientific research may contribute to and strengthen the regulatory process. While the views expressed are shared by

[2] By using the term "academic scientists" we refer to ourselves as persons engaged in scientific research while also being active in the academic milieu of a teaching university.

many colleagues in the scientific community, this brief is filed by the scientists as individuals and not as representatives of an organization or institution.

SUMMARY OF ARGUMENT

Section 6(b)(5) of the Act requires that OSHA develop and promulgate standards on the basis of "research, demonstrations, [and] experiments". In that connection, there is a well-ordered, four-step process of scientific inquiry to deal with questions such as those regarding skin absorption of substances such as benzene. This four-step scientific inquiry involves analysis of existing information, identification of informational gaps, completion of specific experiments to close those gaps, and evaluation of experimental and other data to reach conclusions based on the exercise of scientific judgment. Much data, including skin absorption data, can be obtained within a two- to four-month period using rodents and other laboratory animals. The types of data which can be obtained within this relatively short period include skin absorption data, acute toxicity data, and skin irritation data.

Had OSHA approached the question of skin contact with benzene from the scientific point of view, using the four-step scientific inquiry outlined above, it would have identified the data needed to reach a sound scientific conclusion on workers' exposure to benzene from dermal contact with mixtures containing that substance. By an inquiry to the scientific community, OSHA would have learned that a number of biomedical research facilities would have been able to generate data on skin absorption of benzene in a two- to four-month period, using a simple and standard procedure. We do

not suggest that all data needed by OSHA can be generated in that short period; however, it happens that skin absorption data come within the two- to four-month category.

The substantial biomedical research establishment in the United States, developed in large measure as a result of extensive government experimental programs, has the capability to provide the scientific data required to implement the OSHA statute. The university biomedical research establishment has not been utilized to any great extent by OSHA because OSHA, unlike some other health regulatory agencies, has not made any systematic attempt to take advantage of the research and experimental capability of the academic biomedical research community. If this Court affirms the statutory objective that OSHA act on the basis of research and experimental data in establishing provisions of its standards, the biomedical research community can assist OSHA in obtaining vitally needed scientific information, in most cases in a reasonable time frame.

ARGUMENT

I. Scientific Approaches To Substantiating Regulatory Action

A. Introduction

When the Congress created OSHA in 1970, it recognized the need for *scientifically valid regulations.* Accordingly, Congress directed that OSHA's standards be based on "research, demonstration, experiments . . ." as well as "the latest available scientific data in the field . . . ." In contrast, some of OSHA's regulations, including the portion of OSHA's 1978 benzene standard banning dermal contact with benzene, were developed with insufficient scientific input.

The scientific component of the second issue in this case[3] is such that in reaching its decision, the Court may find it helpful to have a greater understanding of the approaches used in the rapidly advancing field of medical scientific research.

This brief first discusses the scientific community's understanding of "research, demonstrations, [and] experiments". It then discusses the way in which OSHA can make appropriate use of science in setting health standards, and the capability of the biomedical research establishment to supply scientific data to meet OSHA's needs.

B. Scientific description of "research, demonstrations, [and] experiments"

When questions are raised regarding the dangers of the possibly toxic dose levels of substances such as benzene, there is a well ordered, four-step process of scientific inquiry.

The *first step* is to gather the existing information by thoroughly searching the available literature. At present, this is a rapid and efficient procedure due to the extensive computer indexing of scientific papers. Scientists also collect unpublished data by attending

[3] This brief relates only to the dermal contact sections of OSHA's benzene standard (29 C.F.R. § 1910.1028(e)(2) and (h)) and in that context considers and discusses the second and third sentences of Section 6(b)(5) of the Occupational Safety and Health Act of 1970 (the "Act"), 29 U.S.C. § 655(b)(5). These provisions require that OSHA act on the basis of "research, demonstrations, [and] experiments" and other scientific information in promulgating standards under the Act. The *amici* recognize that the requirement that OSHA act on the basis of scientific information also relates to the first issue in this case, but in a different context, which is not addressed in this brief.

conferences and visiting the laboratories of their colleagues. From these sources, there are three types of available data: 1) data from experiments that have not as yet been duplicated; 2) data that have been verified by another group of independent scientists; and 3) data that appear to be contradicted by another group.

The *second step* is to identify the gaps between the information available, and the information needed to clarify those gaps. The scientist studies each area to determine which can be answered most rapidly and reliably, at reasonable cost, and also which areas might be a key that could narrow more than one gap.

The *third step* is to define the specific experiments needed to close the gaps. A major part of this is the identification of the multiple variables inherent in biomedical research which need to be controlled. For example, in considering dermal exposure to benzene, some of the variables requiring control include: the amounts; concentrations; duration; and anatomic site. The experiments considered would include use of laboratory animals, as well as perhaps case-controlled epidemiologic studies in the longer term.

The *fourth step* is to evaluate the experimental and other data to reach conclusions based on the exercise of scientific judgments.[4] An essential aspect of evalu-

[4] Statistical evaluation of numerical data, with a determination of its "statistical significance", is central to good science. These well-defined, simple equations that all scientists learn while in training determine whether differences between the experimental and control groups are "statistically significant" and are unlikely to have occurred by chance; this is most often expressed as the "p value" or "level of confidence."

ating new data is to determine whether it fits logically with the results of other research. If it does, then a comprehensive picture may emerge. If it does not, then the reasons for "not fitting" must be explained through consultation with peers, to search for overlooked variables.[5]

C. Types of data that can be generated, and time periods involved

Depending on the type of data needed to narrow information gaps, different time periods are necessary to conduct the research. If concerted efforts are made, much acute toxicity data can be obtained within a two- to four-month period using rodents and other laboratory mammals. Research concerning long-term ill effects requires 12-24 months and is generally carried out in rodent models that have a natural life-span of 2-3 years.

A wide variety of sophisticated *acute toxicity* data can be generated in 2-4 months, including the following:

1. The amount and rate of absorption via skin, aerosol, and oral intake.

2. The distribution of absorbed material to different organs and mode of excretion or destruction.[6]

[5] Review of the data by peers for adequacy of experiments is crucial for this step. Part of the interaction with peers involves repetition of the experiments by independent groups of scientists to test for reproducibility of results, provided the same protocol is used.

[6] Specifically labelled toxic chemicals, using radioisotopes of carbon (^{14}C), or hydrogen (^{3}H), permit a unambiguous tracing of a chemical into all parts of the body and body fluids; retention and excretion can thereby be determined. Other toxic substances may be detected through their characteristic structure, or their conversion to a distributive metabolite; the use of modern analytic methods such as gas chromatography/mass spectrometry (GC/MS) with a computerized library of mass spectrometry structures, or high pressure liquid chromatography (HPLC), permit the detection of very minute quantities of chemical substances, even in large volume organs such as the liver and brain.

3. The acute effects on the structure and function of vital organs (brain, lungs, heart, liver, kidneys, etc.).[7]

4. Determination of the above (1-3) on different species, at different ages, and under specific physiology conditions such as pregnancy and embryonic states.[8]

II. OSHA Should Make Appropriate Use Of Science In Setting Health Standards

The benzene case seems to be an example where OSHA could have made use of the American scientific

[7] Examination of the structure of tissues from autopsied animals can be accomplished within 24 hours. The function of vital organs can be assessed in varied ways. Brain function can be examined by behavioral studies, in terms of learning and memory, or electrodes may be placed under anesthetic into different parts of the brain to study reflexes and individual nerve cells; this may take between 2-8 hours per rodent. Similarly, tests of cardiac, pulmonary, liver and kidney function may be done on intact animals by materials injected into the blood, and analyzing blood chemicals.

[8] Effects on humans can often be determined through retrospective studies of exposed individuals, provided adequate medical records are available, together with appropriate controls that have been matched for age, sex, race, socioeconomic status, habits such as alcohol and tobacco, and nutritional status. Retrospective epidemiology studies like this can be accomplished within four months.

community in making regulatory decisions to protect workers. We do not know when OSHA first decided to regulate occupational exposure to benzene. The explanation for OSHA's regulatory decision first appeared when OSHA issued an Emergency Temporary Standard ("ETS") in 1977.

OSHA presumably knew at the time it issued the ETS that an important issue was raised regarding dermal contact. The two obvious potential toxic effects from dermal contact are dermatitis and absorption of benzene through the skin.

Perhaps the best approach for protecting workers would have been the scientific one, as contemplated by the statute. OSHA could have sought to determine what information was needed to support a reasonable regulation based on sound scientific data. In doing so, OSHA could have followed the four-step scientific inquiry outlined above.

Had OSHA done so, it would have identified the data needed to reach a sound scientific conclusion on the exposure to workers by absorption from dermal contact with mixtures containing benzene. By a simple inquiry to the scientific community, OSHA could then have determined the length of time it would take to generate that data.

The question of whether the skin absorbs benzene involves a relatively simple and standard procedure. A number of biomedical research facilities would be able to generate data on skin absorption in a two- to four-month period.

It is *not* suggested that all the data needed for OSHA can be generated in two to four months, but it happens

that skin absorption data fall within the two- to four-month category. We further recognize that there may be other situations where the hazard is such that OSHA could not reasonably await the outcome of experiments which require two to three years to complete. We believe, however, that if OSHA establishes priorities for substances it proposes to regulate, the need for data can be identified sufficiently *in advance* of the issuance of regulations, and in many cases the necessary data can be generated before the completion of the regulatory procedure.

From a scientific view, a sound decision cannot be made without valid data from research and experiments. It seems incongruous, from a scientific point of view, that OSHA should purport to issue a regulation to control absorption of benzene by dermal contact when OSHA believed that the data on skin absorption were "extremely limited" and "not definitive". To issue a regulation on this basis is not consistent with the concept of a statute that directs reliance on "research and experiments", particularly when the scientific data can be secured easily, reliably, and in a short time.

The Court of Appeals concluded that OSHA had not followed the Act by relying on "old and inconclusive" data when scientific data on skin absorption were "readily available". Our previous description of data which can be developed in a two- to four-month period would lend support to that conclusion and provides a basis on which this Court can determine whether it was reasonable for OSHA to act on the basis of the data before the Agency.

We do not offer a generic definition of data that are "readily available". From a scientific point of view,

whether data are "readily available" must be judged in the light of the need for data. Where immediate, emergency action is imperative, time becomes critical in deciding what information is readily available. It appears to us that the procedures OSHA followed in the benzene case did not make optimum use of the available time to develop a sound regulation. OSHA presumably knew months in advance of the issuance of the final regulation that the data on skin absorption were not adequate, and that a real need existed. There would have been sufficient time to obtain the needed data, had OSHA pursued the direction from Congress to issue standards based on experiments and research.

III. The Biomedical Research Establishment Has The Capability To Supply Scientific Data Required To Implement The OSHA Statute

The biomedical establishment in the United States is large and well staffed. The university biomedical research establishment provides a good example of these capabilities.

There are approximately 200 identified university research centers that carry out major biomedical research, largely with funds from the National Institutes of Health, the National Science Foundation, federal contracts and other sources. Within these 200 biomedical research centers there are approximately 15,000 senior level scientists (full-time, and tenured as associate and full professors), plus 25,000 junior level scientists (post-doctoral fellows and assistant professors); the technical research support staff is estimated at 20-40,000 and includes laboratory technicians, and animal care personnel. Many of these institutions have large numbers of additional personnel, but the above cited numbers reflect estimates of those engaged in full-

time research; it does not include those who are predominantly providing clinical or educational services.

The biomedical capabilities of the United States have been developed as a result in large measure of the extensive experimental programs of the National Institutes of Health, the National Science Foundation, and other governmental programs. Up to the present, the university biomedical research establishment has been geared to U.S. research programs originated by the academic scientists. The capabilities were designed to carry out those programs. The university biomedical research establishment has not been utilized to any great extent by OSHA because OSHA has not made any systematic attempt to take advantage of the research and experimental capability of the academic biomedical research community.

Traditionally, OSHA has tended to be passive so far as research and experimentation are concerned. If scientific data were presented at a hearing, OSHA considered them. OSHA has not been in the forefront of identifying and seeking out the data which it needs for scientifically based regulations.

OSHA could take *affirmative action* in securing the new data needed by streamlining short-term research contracts through a list of "pre-qualified contractors." For example, there are several potential administrative mechanisms to cut "red tape" and allow greater joint ventures between OSHA and the university scientists. It is *not* the purpose of this brief to advocate any specific administrative means for streamlined contracting, but such means are readily formulated. We would suggest that if streamlined contracting were to be created, that on any one major scientific question, contracts be awarded simultaneously to three independent

groups. If all three followed the same protocol of procedures and analyses, then reproducible data would be more rapidly forthcoming.

In considering the capabilities of the U.S. academic medical research community to be of assistance to OSHA, it is fair to question why current data, most of which has been generated by the university scientists, are not sufficient for OSHA's needs.

The principal reason is that the scientists of the university biomedical research establishment are not responsible for, nor do they have information on, regulatory priorities. Since OSHA has rarely indicated an interest in using the biomedical establishment to provide the research and experimental data OSHA needs, the data have not been developed. Rather, the capabilities for research and experimentation are designed to respond to U.S. research programs initiated by the academic scientists. Data needed by OSHA are generated only incidentally as part of those research programs.

It is not reasonable to expect experimental scientists to predict the needs of OSHA for new scientific data. If, however, the Court affirms the statutory objective that OSHA rely on research and experimental data, then we believe OSHA can no longer be the passive receptor of information which in many cases could be insufficient for OSHA's needs. If, as we understand the statute, the intention is that OSHA rely on research and experimental data, then the scientific approach to the evaluation of data, identification of gaps, and the development of data to fill the gaps dictates that OSHA take an *active,* rather than a passive role toward the development of new and vitally needed information.

If OSHA assumes the appropriate attitude toward science, its needs can be served by the biomedical establishment.

A major objection that may be made by OSHA's relying on new scientific data obtained through streamlined contracting mechanisms is that data are frequently the subject of scientific controversy. Scientific controversy is more often seen with respect to long-term testing and chronic effects, and in general, there is relatively less controversy with respect to short-term (2 to 4 months) tests dealing with acute toxic effects. The simultaneous conduct of short-term research by three different groups would lend further assurance of less controversy. The fact that some controversy may exist should not lead to the nihilistic conclusion that OSHA cannot rely on new research and experimental data.

The basic proposal of this brief, that science be utilized to help create a better workplace through greater cooperation with a government regulatory agency, is not new. Rather, it has been used by others, including the Environmental Protection Agency, through the use of contracts and scientific advisory committees. An appreciation of the increasing importance of science, as the basis for public policy decisions by regulatory agencies has resulted in the following, as but a few examples: an inspection program of laboratories by the Food and Drug Administration; the development of governmental standards of good laboratory practice; and the coordination by the regulatory agencies of information on research programs. It appears fully appropriate for OSHA to exercise its statutory duty to seek out new data, for regulatory purposes, through

"... research, demonstrations, [and] experiments...."
The nation's academic research community can help.

CONCLUSION

The attitude we have attempted to convey is that if, as is increasingly true, science becomes an important basis for public policy decisions, scientific regulatory agencies have an obligation to assure that sound science is used. We have suggested ways in which a program to accomplish this purpose might be approached. We urge that if OSHA takes the initiative which we believe it should, then the scientific community can respond to OSHA's needs.

What we are proposing is the opposite of delay or awaiting "one more study". If OSHA acknowledges its responsibility to identify the data it needs and the scientific community is informed of OSHA's priorities, the data can be generated in most cases in a reasonable time frame.

OSHA can see to it that the data are generated with scientific rigor and can validate data by replication and peer review. Scientifically sound regulation based on "research, demonstrations, [and] experiments" which constitute the "best available evidence" will be the result, rather than questionable regulations based on incomplete data.

Respectfully submitted,

JAMES R. RICHARDS
1101 17th Street, N.W.
Washington, D.C. 20036
Counsel

July 30, 1979

JUL 31 1979

MICHAEL RODAK, JR., CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1978

Nos. 78-911 and 78-1036

INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
Petitioner

RAY MARSHALL, SECRETARY OF LABOR,
Petitioner.

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*

BRIEF AMICUS CURIAE OF THE CHOCOLATE MANUFACTURERS ASSOCIATION

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IN THE

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INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
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RAY MARSHALL, SECRETARY OF LABOR,
Petitioner.

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*

BRIEF AMICUS CURIAE OF THE CHOCOLATE MANUFACTURERS ASSOCIATION

I. INTEREST OF THE AMICUS CURIAE

In the opinion below the Fifth Circuit held that the Occupational Safety and Health Administration, when it promulgates an occupational safety and health standard under the Occupational Safety and Health Act of 1970, 29 U.S.C. §§ 651, *et seq.*, has a statutory obligation to identify the expected costs and benefits of the standard and to "determine whether the benefits expected from the standard bear a reasonable relationship to the costs imposed by the standard." 581 F.2d

493 at 503. The Fifth Circuit went on to find that, in this case, OSHA had failed to make the necessary determinations.

The Chocolate Manufacturers Association (CMA) is filing this *amicus* brief solely to underscore the importance of the basic principle applied by the Fifth Circuit: that OSHA standards must be "reasonable" in the sense that both the benefits to be derived and the costs of compliance must be considered.

CMA is a trade association whose member companies are engaged in the business of manufacturing chocolate products. CMA members are not familiar with the benzene standard which is under review in this case, and they have had no experience under it. Their concern that OSHA rules be "reasonable" stems directly from their attempts to comply with other OSHA regulations: those which limit exposure of workers to noise.[1] CMA believes that the experience of industry under OSHA's noise regulations may be relevant to any general interpretation of the Occupational Safety and Health Act.

II. ARGUMENT

OSHA's noise regulations require manufacturers to use all "feasible" methods to reduce physical noise levels in their plants to allowable limits. Only if there

[1] OSHA's noise standard provides in relevant part that:

> When employees are subjected to sound exceeding those listed in Table G-16, *feasible administrative or engineering controls shall be utilized.* If such controls fail to reduce sound levels within the levels of Table G-16, personal protective equipment shall be provided and used to reduce sound levels within the levels of the table. 29 C.F.R. § 1910.95(b)(1). (emphasis supplied)

is no "feasible" way to reduce worker exposure to noise to those limits is an employer permitted to rely upon the use of earplugs and personal protective equipment to protect workers' hearing. The cost of redesigning and rebuilding factories and equipment is obviously enormous when compared to the alternative cost of issuing individual hearing protectors. Food processors face particularly difficult problems in complying with noise requirements because good sanitation practices (and the requirements of the Food and Drug Administration) require the use of hard, easily cleanable surfaces rather than soft, sound absorbing material in their plants.

In enforcement actions arising under the noise standard, OSHA has consistently taken the position that it has no obligation to weigh economic costs. OSHA's position on noise control, like the position it advances in this case, is that it is required only to show that an engineering solution is technically possible and that it will not jeopardize the solvency of the employer.[2]

In the context of noise control, the courts have emphatically rejected OSHA's cost-blind approach to regulation. In *Turner Company* v. *Secretary of Labor, et al.*, 561 F.2d 82, 83 (1977), the Seventh Circuit looked to the "clear intent of Congress and the pur-

[2] *See*, for example, Turner Company v. Secretary of Labor, et al., 561 F.2d 82, 83 (7th Cir. 1977), in which OSHA argued that it was proper for it to limit its "consideration [of costs] to the financial ability of an employer to pay for technological controls irrespective of compelling alternatives."

In a pending action before the Ninth Circuit, OSHA is arguing that "engineering [noise] controls are economically feasible [whenever] they do not threaten financial viability of an employer." Brief for the Secretary of Labor in Marshall, *et al.* v. Castle & Cooke Foods, *et al.* (No. 77-2665) at 24 (filed February 3, 1978).

pose of the Occupational Safety and Health Act" and concluded that the term "feasible" as used in the noise regulation "must be given its ordinary and common sense meaning of 'practicable.'" The *Turner* Court applied a standard originally established by the Occupational Safety and Health Review Commission and admonished OSHA that it must "realistically consider the hazards presented by the excessive noise . . . and determine whether the health benefits to employees who are already equipped with personal protection equipment justified the . . . costs . . . for engineering controls." 561 F.2d at 86. The Sixth Circuit approved and applied the *Turner* test and noted that: "a consensus is developing among the circuits that the term 'feasibility' [as used in the noise regulation] should encompass both technological and economic feasibility." *RMI Co.* v. *Secretary of Labor, et al.*, 594 F.2d 566, 571-72 (1979).

Of central importance to both circuits was the failure of OSHA to weigh the availability of less costly methods to achieve the health goals of the standard.

The requirement that OSHA must determine whether the benefits "expected from a standard bear a reasonable relationship to the costs imposed by the standard" is nothing more than a recognition that capital resources are finite and that finite resources must be allocated in a rational way. If workers' hearing can be protected by means of inexpensive hearing protectors and regular audiometric testing, it is neither rational nor "reasonable" to require massive capital investments in plant and equipment. Further, OSHA regulation does not exist in a vacuum. Manufacturers are simultaneously subject to regulation by many agencies with many different goals. It is obviously not possible

to allocate finite resources in a rational fashion if the test applied by each regulatory agency is whether the capital expenditures required by the regulations of that agency alone will endanger the financial health of the industry. Rational allocation of resources is possible only if each agency is required to identify and evaluate the benefits of its proposed regulations together with their costs. It was partially in recognition of the fact that resources are finite that Congress expressly required OSHA to measure its standards by the test of "reasonableness."[3]

For the same reason, the President of the United States has adopted as the policy of the executive branch of the government that regulations "shall not impose unnecessary burdens on the economy" and that all executive agencies shall consider "alternative approaches" to ensure that "the least burdensome of the acceptable alternatives has been chosen." Executive Order No. 12044 (Improving Government Regulations), 43 Fed. Reg. 12661, 62 (1978).

The Chocolate Manufacturers Association is not familiar with the record before the agency in this case and therefore takes no position on whether OSHA properly considered costs and benefits in this particular case. CMA's concern is that the Court's opinion not diminish the obligation of OSHA in regulating other hazards, including noise, to be sensitive to the economic costs of its regulations and to determine whether the

[3] The statute, 29 U.S.C. § 652(a), requires that OSHA regulations be "reasonably necessary or appropriate." In the context of tort law, one commentator has said:

> "Reasonableness is determined by a straight-forward balancing of cost and benefit." Fletcher, Fairness and Utility in Tort Theory, 85 Harv. L. Rev. 537, 542 (1972).

costs of a proposed regulation are reasonable in light of the benefits to be derived from it.

III. CONCLUSION

The CMA respectfully urges this Court, whether it affirms or reverses the decision below, to affirm the basic principle that OSHA must identify and consider both the costs of compliance and the benefits of the regulations which it proposes.

Respectfully submitted,

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1979

No. 78-911

INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
Petitioner

v.

AMERICAN PETROLEUM INSTITUTE, ET AL.

No. 78-1036

RAY MARSHALL, SECRETARY OF LABOR,
Petitioner

v.

AMERICAN PETROLEUM INSTITUTE, ET AL.

On Writ Of Certiorari To The United States Court Of Appeals For The Fifth Circuit

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BRIEF FOR THE AMICUS CURIAE CHAMBER OF COMMERCE OF THE UNITED STATES

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BRIEF FOR THE AMICUS CURIAE CHAMBER OF COMMERCE OF THE UNITED STATES

INTEREST OF THE AMICUS CURIAE

The Chamber of Commerce of the United States is the largest business federation in the United States, consisting of over 3700 State and local chambers of commerce and trade and professional associations, and a direct business membership in excess of 81,000 business firms and individuals.

The present case is of vital concern to the Chamber's members, for four reasons.

First, the position taken by OSHA — that it may issue standards without any estimate of their effectiveness in benefiting worker health — will inevitably increase the already substantial costs imposed on American business by OSHA regulation. A recent study of OSHA's policy for regulation of carcinogens estimated that it will result in $9 to 88 billion capital costs and $6 to 36 billion annual costs, depending on how it is applied.[1]

Second, the Chamber's members are concerned that the approach taken by OSHA will ultimately lead to less effective protection for their employees' health. At the rate of expenditure represented by the benzene standard (conservatively estimated to be at least $240 million per case of cancer avoided) it would take an annual expenditure far in excess of the Gross National Product to solve the occupational cancer problem — with nothing left over to address other societal purposes, including other causes of cancer and other health and safety problems.[2]

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[1] Booz, Allen & Hamilton, Inc., Preliminary Estimates of Direct Compliance Costs and Other Economic Effects of OSHA's Generic Carcinogen Proposal on Substance Producing and Using Industries (February, 1978). This study was directed to OSHA's still pending proposal for a generic regulation on controlling occupational carcinogens. 42 Fed. Reg. 54148 (October 4, 1977).

[2] As discussed in note 5 infra, the testimony that the standard represents an expenditure of $300 million per cancer avoided, should be revised to $240 million in light of OSHA's final cost estimates.

There are approximately 360,000 cancer deaths annually in this country, or about 1,000 per day. See OSHA, Identification, Classification and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk, 42 Fed. Reg. 54148, 54150 (October 4, 1977).

Estimates of the portion of the overall cancer rate attributable to occupational causes range from 1% to a recent HEW estimate of 20% (attributable in large portion to asbestos). See National

The Chamber believes that more lives can be saved and serious injury prevented, by OSHA standards which offer a larger return for the resources expended. Yet unless OSHA is required to estimate the effectiveness of its standards there is no assurance that these regulations will ever even approach the maximum lifesaving potential of the resources expended.

Third, OSHA's refusal to consider the effectiveness of its standards is at variance with the positions taken by the Food and Drug Administration, the Environmental Protection Agency, the Consumer Product Safety Commission and the National Highway Traffic Safety Administration — all of which regulate the Chamber's members. If a decision of this Court were to endorse OSHA's position, and the decision were applied to other agencies, there could be disastrous effects on the level and effectiveness of regulation across the entire field of federal health and environmental control.

Finally, the Chamber is concerned that OSHA's position will lead to public disillusionment and eventually loss of support for any serious effort to alleviate the cancer problem in this country. OSHA's position is basically that all carcinogens must be regulated to the point of maximum affordable cost, regardless of the enormous degree of variation in the risks presented, which differ by more than a millionfold.[3] However, this philosophy of regulation runs

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[Footnote 2 cont.]

Cancer Institute, National Institute of Environmental Health Sciences, National Institute for Occupational Safety and Health, Estimates of the Fraction of Cancer in the United States Related to Occupational Factors (September 15, 1978), at p. 1. An estimate of 10% would involve 100 deaths a day, meaning that at an expenditure rate of $240 million per case, the total for 12 weeks would use up the Gross National Product ($2 trillion).

[3] The potency of different carcinogens varies by as much as a million times; and this difference is magnified by large differences in the levels of exposure. See respondents' brief, Addendum C.

the danger of depleting not only economic resources, but also the public support needed for effective anti-cancer measures. By refusing to distinguish between severe and remote cancer hazards, OSHA contributes to an already common public attitude that "everything causes cancer, so what's the use." Indeed, this attitude was eloquently expressed last year by a popular columnist:

> Not just aerosol deodorants and hair sprays, but the very air we breathe and the water we drink and the sunshine that warms us have all been identified as carcinogens. I even remember reading a report that linked sex with cancer. After a while, the mind refuses to accept such warnings * * *.
>
> But for most of us it's not practical to give up meat or vegetables grown with the aid of fertilizer and pesticides. We are not going to give up air or water or sunshine.
>
> What's more likely — in fact, what is already happening — is that we'll give up on the scientists who tell us these things.
>
> *It would help if scientists would tell us which substances are more dangerous than which others, or in what levels these dangerous substances can be treated as benign.*
>
> But they won't tell us these things; they say they don't know.
>
> *When nearly everything is demonstrated to be dangerous, we are forced to behave as though nothing is dangerous.* We will make our wry little jokes (calling cigarettes 'cancer sticks,' for instance) and go on as before.

Raspberry, "Those Hamburger Warnings," Washington Post, May 19, 1978 (emphasis added).

As we shall demonstrate, Mr. Raspberry's remarks are not completely accurate with regard to other federal health and environmental agencies, which do make an effort to assess the degree of public health hazard presented by a suspected carcinogen, before regulating. However, OSHA refuses to follow the other agencies' practice and now seeks this Court's endorsement for its aberrant views.

QUESTION PRESENTED

Whether OSHA must estimate the health benefits expected to result from its issuance of an occupational standard.

SUPPLEMENTAL STATEMENT OF THE CASE [4]

In 1971, OSHA adopted a standard of 10 ppm (parts per million) for occupational exposure to benzene. 29 C.F.R. §1910.1000 Table Z-2. The present proceeding involves OSHA's issuance of a regulation lowering the standard tenfold, to 1 ppm.

OSHA's proposal to lower the standard was based on studies indicating benzene had caused an excess incidence of leukemia among certain groups of workers. These studies (summarized in the opinion of the Court of Appeals, Pet. App. 8a, n. 13) involved exposures to benzene of 100 ppm and above.

At the hearing on the proposed standard, the industry argued 1) that at the levels of exposure represented by the current standard (10 ppm), there is no demonstrated risk of leukemia, and 2) that even if a risk exists, at the 10 ppm current level the risk is extremely low. In this connection, one witness (Dr. Richard Wilson of the Harvard Energy and Environment Policy Center) testified as to the level of risk, if any, present by occupational exposure to benzene at 10 ppm. He found it to be comparable to the

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[4] The Supplemental Statement is not a complete statement but rather sets forth those facts germane to the arguments presented by the Amicus.

risk that each individual in the population runs of dying in any one year from drowning or from fires and hot substances. (A 171, 172). Another comparison made by Dr. Wilson was that two weeks of exposure to benzene at 10 ppm presents a hazard equivalent to one day of air pollution in Boston or Washington, one gallon of chlorinated drinking water, or one-half bottle of wine. (A 174).

Based on OSHA's data that about 30,000 workers now have benzene exposures between 10 ppm and 1 ppm, Dr. Wilson concluded that the new standard would save at most one case of leukemia and one other cancer every six years. (A 176). Based on OSHA's preliminary cost estimates, Dr. Wilson concluded that the standard would cost at least $300 million for every life saved (a figure which should be revised to approximately $240 million in light of OSHA's final cost estimates) and might even cost more lives than it saved (since some construction work would be required, and generally one life is lost for every $20 million spent in construction). (A 81).[5]

In issuing its final standard, OSHA rejected the industry's contention that benzene had not been demonstrated to present any risk at the level of the current standard. The court of appeals accepted OSHA's conclusion on this point, which is not contested in this Court. (Pet. App. 18a).

OSHA also rejected the industry contention that it should attempt to estimate the *degree* of risk presented by exposure at the currently-required 10 ppm, and in that context assess whether the standard was "reasonably necessary" or "feasible" within the meaning of sections 3(8) and 6(b)(5) of the Occupational Safety and Health Act. 29 U.S.C. §§652(8), 655(b)(5).

[5] OSHA's final cost estimates were $187-205 million first-year operating costs, $266 million engineering control costs, and $34 million recurring annual costs (Pet. App. 17a). At an interest rate of 10%, the annual charge for the total first-year costs plus capital costs ($471 million) would be $47 million. Adding the $34 million recurring costs produces a total annual cost of $81 million. At the rate of two lives every six years or one life every three years, this produces a total of $243 million per life.

The court of appeals reversed OSHA on this point, holding that OSHA must "estimate the extent of expected benefits in order to determine whether those benefits bear a reasonable relationship to the standard's demonstrably high costs." (Pet. App. 19a).

SUMMARY OF ARGUMENT

We endorse and adopt the discussion in respondents' brief, demonstrating that OSHA's summary rejection of any serious attempt to estimate the health benefits of the benzene standard violates the requirements of the Occupational Safety and Health Act.

OSHA's position is at odds with the position taken by the other key federal agencies with responsibility for health, safety and environmental regulation — Food and Drug Administration, Environmental Protection Agency, Consumer Product Safety Commission and National Highway Traffic Safety Administration. All these agencies have performed estimations of health benefits in connection with their regulations, thus demonstrating disagreement with OSHA's position that such estimates are too uncertain to be used for regulatory purposes. Moreover, these other agencies have frequently performed health risk estimations under laws that are either similar to the Occupational Safety and Health Act, or are stricter (in the sense of requiring regulations that assure "safety" without explicit statutory authority to consider cost). In light of the other agencies' practice, OSHA cannot summarily dismiss the view that health benefit estimates can and should be performed.

It is argued that health risk estimations are too uncertain to "precisely quantify" the benefits of regulation.

However, no one has ever claimed that "precise quantification" could be provided by health risk estimation, or is necessary for regulatory purposes. The other federal agencies, when they perform risk estimations, treat them as approximations, and yet have found such approximations to be useful for regulatory purposes. Nothing in the Occupational Safety and Health Act requires precise quantification.

Moreover, there are at least two techniques for dealing with uncertainty. The witnesses in this case, as well as the other federal agencies, have compensated for the lack of precision in health risk estimates by utilizing "conservative" or "pessimistic" assumptions at key points of uncertainty — i.e., taking high estimates at uncertain points in the analysis — so as to avoid the danger of underestimating risk. Another technique (which the Chamber believes to be preferable) is to obtain from the scientists a "most probable" estimate of the level of risk together with a statement of the range of uncertainty, and then to have the decision makers apply whatever safety factors appear to be appropriate in light of that uncertainty and other relevant factors. However, OSHA does not even discuss why it rejects these techniques as ways of dealing with the problem of uncertainty in health risk estimation. Instead, OSHA simply says that health risk estimation is uncertain and therefore cannot be used. This is simply not adequate.

OSHA also contends that "cost benefit criteria" are inconsistent with the OSH Act. However, this misses the point. No one in this case has suggested that one must place a price tag on human life, and then decide whether an OSHA regulation is "worth it" in terms of that price tag. Instead, the point is that because the resources available for occupational safety and health are limited, they should be spent where they will have the maximum effectiveness in terms of lives saved. In order to determine whether its standards approximate their maximum life-saving potential, OSHA must have some rough idea as to

what the health benefit of each standard is. Only in this manner can OSHA achieve its statutory goal "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions." 29 U.S.C. §651. Standards which save lives at the rate of only one per several hundred million dollars spent will clearly not achieve anything close to the maximum life-saving potential of the available resources.

ARGUMENT

I. OSHA HAS NO VALID BASIS FOR ITS REFUSAL TO ASSESS THE EFFECTIVENESS OF THE BENZENE STANDARD

As respondents' brief demonstrates, OSHA's preamble to the benzene standard, as well as its statements and actions on other occasions, are so confusing that it is impossible to determine what the basis is for its rejection of any serious effort to estimate the health benefits of the benzene standard.

What is clear is that OSHA misunderstands the nature and utility of risk estimation when it claims: 1) that the data are not sufficiently certain to "precisely quantify" the health benefits of the regulation (Pet. App. 162a); 2) that "cost-benefit criteria" are inconsistent with the Act and would involve the impossible task of quantifying the value of life (Pet. App. 162a, OSHA Br. p. 62, n.52); and 3) that cost-benefit analysis is inappropriate as a matter of equity, because the worker bears the risk while the consumer obtains the benefit (OSHA Br. p. 47).

None of these reasons is an adequate basis for OSHA's position.

1) The existence of uncertainty is not a sufficient basis for refusal to assess the health benefits of a regulation.

OSHA's summary dismissal of the evidence concerning the miniscule degree of health benefits to be expected from the benzene regulation as "uncertain" and lacking "preci-

sion," overlooks the fact that there are at least two ways of dealing with the conceded uncertainties in risk estimations.

In both Dr. Wilson's testimony, as well as in the numerous risk assessments performed by EPA and other agencies (including EPA's assessment of benzene), the question of uncertainty is handled by making "pessimistic" or "conservative" assumptions — i.e., at points of uncertainty, the high assessment of risk is made.[6] In particular, EPA's estimation of benzene risk used a so-called linear model for extrapolating risk at low exposures from historical high-exposure data, on the ground that this model "is expected to give an upper limit to the estimated risk." (A 15).[7]

This approach to dealing with uncertainty has been described and endorsed in the recent report of the Interagency Regulatory Liaison Group (IRLG), a group consisting of the CPSC, EPA, FDA and OSHA. In this report,

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[6] An industry consultant who estimated the health benefits of the regulation at one case every 15 to 38 years, listed three "conservative assumptions" in Wilson's testimony that accounted for Wilson's higher estimation of risk:

a. *All* leukemias (not just ANLL [acute nonlymphocytic leukemia, a form specifically associated with high benzene exposures]) are benezene related.

b. For every benzene leukemia there would be another cancer at another site in the body due to benzene exposure.

c. Benzene exposure of those currently exposed to 1 to 10 ppm benezene would be far less than 1 ppm if a new standard were introduced.

(Lamm affidavit, A 34).

[7] The linear model assumes that cancer incidence varies in direct proportion to exposure. Dr. Wilson also used this model. (A 89). By contrast, other models assume that at low exposures the cancer incidence is much less than a linear model would predict. OSHA itself appears to have endorsed the linear model in its proposal for a generic policy for regulation of suspected occupational carcinogens. 42 Fed. Reg. 54148, 54167 (October 4, 1977).

the IRLG specifically addresses the question of estimating the risk of exposure to carcinogens:

> Despite the uncertainties, risk estimates can be and are being made, not only by some regulatory agencies but by other scientific bodies. *Because of the uncertainties, however, and because of the serious public health consequences that could ensue if the estimated risk were understated, it has become common practice to make cautious and prudent assumptions wherever they are needed to conduct a risk assessment.* This approach has a precedent in other areas of public health protection where similar problems arise because of gaps in knowledge. [Citation omitted] *Thus current methodologies, which permit only crude estimates of human risk, are designed to avoid understatement of the risk.*

Scientific Bases for Identifying Potential Carcinogens and Estimating Their Risks, Report of the Interagency Regulatory Liaison Group (IRLG) Work Group on Risk Assessment, Part III, "The Quantitative Estimation of Risk," 44 Fed. Reg. 39858, 39871 (July 6, 1979) (emphasis added).

The Office of Science and Technology Policy, in the Executive Office of the President, has described an alternative approach to dealing with uncertainty, which the Chamber favors. Under this approach, there would be generated a scientific estimate of the "most probable" level of risk, together with a statement of the range of uncertainty in the estimate. It would then be the function of the decision-makers to apply whatever safety factors were deemed appropriate, in light of the uncertainties in the scientific estimate, the type of health risk involved, the social costs of regulation, and any other relevant factors.[8] This ap-

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[8] The OSTP Report describes these two techniques for dealing with the problem of uncertainty:

> For each term in the equation, one could then generate a range of potential values based upon existing data. Which

proach is preferable to the "conservative assumption" technique, because it encourages the scientists to improve their techniques of estimation rather than freezing the evolving science of risk estimation into a particular format, and it brings out into the open policy forum the choices that must be made regarding the size of the margin of safety to be built into regulatory decisions — rather than hiding these choices in an often high technical scientific analysis.[9]

[Footnote 8 cont.]

of these values, however, should be entered into the equation for an accurate asessment of overall risk? One approach is to use the high risk estimate for each term in the equation. This results in the most extreme estimate possible for risk to humans. Another approach is to use the most likely value for each term, including confidence intervals which express the precision of each estimate. This latter approach generates the risk estimate which has the greatest probability of being accurate and which also makes clear the uncertainty involved.

Office of Science and Technology Policy, Executive Office of the President, Identification, Characterization, and Control of Potential Human Carcinogens: A Framework for Federal Decision-Making (February 1, 1979), at p. 18.

[9] A recent article by Judge Bazelon, discussing the question of risk estimation, stresses the importance of keeping value judgments out of the scientific component of the decision, so that they may be explicitly acknowledged and discussed by the policy-makers. This, we believe, is the most important reason why the "most probable" risk approach is preferable to the "conservation assumption" technique:

> The growing use of analytic tools such as cost-benefit analysis magnifies the chance that unrecognized value judgments will creep into apparently objective assessments. Even the most conscientious effort by experts,not to exceed their sphere of competence may be inadequate to safeguard the validity of the decision-making process. * * * *
>
> Courts, standing outside both scientific and political debate, can help to make sure that decision-makers articulate the basis for their decisions. In the scientists' realm — the sphere of fact — courts can ask that the data be described, hypotheses articulated, and, above all, in those areas where we lack knowledge, that ignorance be confessed. In the political realm — the sphere of values — courts can ask that de-

Of course, it is not for this Court to choose between various forms of risk analysis. Rather, the choices must be made by the various regulatory agencies that deal with health and safety issues. However, here OSHA has not even addressed the issues, but instead has summarily stated that it cannot accept "uncertainty." This is simply not an adequate basis for what OSHA has done.

In the area of health and environmental regulation, the courts have stressed that the government must act at the "frontiers of knowledge"; that substantial uncertainties are necessarily involved; but that uncertain data may nevertheless be the basis for action. *Ethyl Corp. v. EPA*, 541 F.2d 1, 24-29 (D.C. Cir 1976) (en banc), *cert. denied* 426 U.S. 941 (1976). See also, OSHA's proposal for a generic carcinogen policy, 42 Fed. Reg. 54148, 54153 (October 4, 1977), discussing its obligation to regulate on the basis of uncertain evidence. The OSH Act itself emphasizes this point, by directing OSHA to set standards on the basis of the "best available evidence." 29 U.S.C. §655(b)(5). With specific reference to carcinogen risk assessment, the IRLG report makes the same point by stating that with present knowledge, assessment of cancer risk provides "a rough estimate of the magnitude of the cancer risks which may be useful in setting priorities among carcinogens and in obtaining a very rough idea of the

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[Footnote 9 cont.]

cision-makers explain why they believe that a risk is too great to run or why a particular trade-off is acceptable. *Perhaps most important, in the nether realm, at the interface of fact and value, courts can help assure that the value component of decisions is explicitly acknowledged, not hidden in quasi-scientific jargon.*

Bazelon, Risk and Responsibility, 65 A.B.A.J. 1066, 1068 (July, 1979) (emphasis added). The degree of conservativism in a regulatory decision is a question in the "political realm" or the "sphere of values", as Judge Bazelon puts it. Thus it should be kept out of the scientific analysis, which should be confined to an estimation of the most probable risk and the range of uncertainty.

magnitude of the public health problem posed by a given carcinogen." IRLG Report, 44 Fed. Reg. at 39872.

When a "rough estimate" is that the regulation would cost $240 million per life saved, the regulation would be unreasonable even if the estimate were overstated by a large multiple (and it may be understated [10]). OSHA cannot avoid the problem by summary and irrelevant references to "uncertainty" and the impossibility of "precise quantification."

2) The conceded impossibility of quantifying the value of human life is not an adequate basis for refusing to assess the effectiveness of a health regulation.

OSHA's decision hints that one of its reasons for refusing to assess the effectiveness of the benzene standard is the impossibility of quantifying the value of human life. (Pet. App. 163a). The same suggestions lurks in OSHA's statement that "cost benefit criteria" are impermissible under the Act. (Pet App. 162a). The Government's brief makes this point more explicitly (at pp. 62-63 n. 52).

In fact, this argument totally misses the point. No one in this proceeding has suggested that it is possible or even desirable to place a value on human life. Instead the point made was that, since resources are limited, the expenditure of several hundred million on this regulation would inevitably mean that several hundred million would not be available to spend on other health and safety regulations; and that if several hundred million spent elsewhere would save more lives, then its expenditure here would mean that the overall health and safety effort would be *less* effective and save *fewer* lives.[11]

[10] Other estimates are that the regulation will save one life every 15 to 38 years, or one life every 83 years. (A 34, A 35).

[11] Dr. Zeckhauser, an economist, testified that much of the cost of the standard represents resources that would otherwise be available for other societal purposes, including protection of health and safety in other areas:

> If a private corporation is in a 50 percent marginal tax bracket, for example, one half of any reduction in profits due to expenditures entailed by regulations will be borne directly by the taxpaying public as a whole. A further fraction would be borne, of course, given reduced taxes on earnings eventually going to shareholders in the form of dividends or capital gains. Of course, much if not most, of the expenditure will not come out of profits. Some will come out of the wages of workers. More will be passed on in the form of higher prices, in general the less elastic is the demand for the product. For example, since the price elasticity for gasoline is low, additional costs in gasoline production will be mostly absorbed through higher prices.
>
> The economic costs we are talking about represent real resources that could be devoted to other purposes in society. For example, in computing the economic costs of the benzene standard, we should recognize that doctors administering tests for benzene exposure to workers will not be available to deliver other medical services. The workers and machines producing monitoring equipment will be taken away from the production of other equipment that might have been used either to save lives, or to serve any other purpose of society.

(A 142).

In other words, it is just because the value of life is infinite, that it is vitally important to spend our limited health and safety dollars in those areas where they will save the most lives. In order to do this, we must have some rough idea of the life-saving potential of any health or safety regulation that is proposed.

The point was summarized in the testimony of Dr. Zeckhauser:

> [W]hen attempting to accomplish some end such as protecting human health, we should direct economic resources where they accomplish the most. If the expenditure of an additional $1,000,000 would save five lives on the highway, but the same expenditure on plant safety would only save one life, then if we chose the plant safety expenditure over the

highway expenditure, we would in effect be sacrificing lives.

(A 140).[12]

OSHA's suggestion that it is impossible to quantify the value of human life is correct, but totally irrelevant. In fact, OSHA has given no reason why it cannot and should not attempt to maximize the effectiveness of the occupational safety and health dollar, and thus best serve the purpose of the OSH Act "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions." 29 U.S.C. §651.[13]

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[12] Dr. Zeckhauser made it plain that estimating the effectiveness of a health regulation does *not* require putting a value on human life:

> I should be explicit. I am not arguing that a cost-benefit approach be employed in formulating policy on occupational safety and health. Such an approach would require that a dollar price tag be attached to a life saved. The value of the lives saved would then be weighed against the resources invested to find the program that had the highest net value. The major objection to this approach is that there is simply no widely accepted precedure for determining the value of lives in contexts such as these.
>
> Fortunately, there is an alternative approach, called cost-effectiveness analysis, that enables us to establish priorities in programs for saving lives. The guiding principle of cost-effectiveness analysis is that for whatever level of resource expenditure we are undertaking, we should attempt to gain the maximum possible level of effectiveness. * * * * The criterion for effectiveness in the occupational health area would be health or lives preserved.

(A 137).

[13] Dr. Zeckhauser conceded in his testimony that OSHA might disclaim responsibility for consistency with other government health and safety agencies, in terms of the level at which standards are considered to be cost-effective. (A 140). However, as Dr. Zeckhauser pointed out, OSHA should "make every attempt to be consistent across the broad sweep of problems encompassed by occupational health and safety." *Ibid.* But without knowing the cost-effectiveness of the benzene standard, OSHA has no way of knowing whether the resources spent there might be more effectively spent and save more lives in some other occupational area.

3) The allegedly inequitable distribution of risk and benefit is an inadequate basis for refusing to estimate the extent of health benefits.

The Government's brief (at p. 47, n.38), although not the OSHA decision, argues that cost-benefit analysis is inappropriate because in the occupational context the worker bears all the risk, while the consumer obtains the benefit (in the form of a lower price). This, the Government argues, is unlike the consumer area, where a risky product (such as a sharp kitchen knife) at least gives the consumer some benefit along with the risk.

However, this argument is also irrelevant. The purpose of estimating the extent of health benefits for occupational regulations is to maximize the number of lives saved by occupational regulations. It is not a question of balancing worker risk against consumer benefit. Rather, it is a question of maximizing worker benefit. Thus the argument of an inequitable distribution of cost and benefit is simply irrelevant.

II. THE PRACTICE OF OTHER FEDERAL AGENCIES DEMONSTRATES THAT THE BENEFITS OF HEALTH AND SAFETY REGULATION CAN BE ASSESSED WITH SUFFICIENT CERTAINTY FOR REGULATORY PURPOSES, AND THAT SUCH ASSESSMENT IS CONSISTENT WITH THE PURPOSES OF HEALTH AND ENVIRONMENTAL LAWS SIMILAR TO THE OSH ACT.

Among the federal health and environmental regulatory agencies, OSHA stands alone in refusing to assess the cost-effectiveness of its regulations. The Food and Drug Administration, the Environmental Protection Agency, the Consumer Product Safety Commission, and the National Highway Safety Administration, have all found it useful to estimate, generally in quantitative terms, the effectiveness of their regulations. Recognizing the uncertainties involved in these estimates, these agencies have nevertheless

found them to be useful for regulatory purposes. In particular, these agencies have attacked the problem of uncertainty by utilizing the "conservative assumption" technique — that is, resolving uncertainties in the direction of the higher health risk, so as to avoid understatement of risk.

The OSH Act requires OSHA to take into consideration "experience gained under this and other health and safety laws." 29 U.S.C. §655(b)(5). There is no evidence that OSHA has done so. The experience of other federal agencies shows that health benefit estimations are sufficiently reliable to be used for regulatory purposes; OSHA cannot dismiss this experience with the conclusory statement that estimates of health benefits are "extremely uncertain" and cannot provide "precise calculations." (Pet. App. 162a, 163a).

In addition, as we shall demonstrate, the various statutory authorities under which other federal agencies have estimated the health benefit of their regulations are frequently similar to the OSH Act (in the sense of requiring regulations to be "feasible" or "practicable"), and in some cases are even stricter than the OSH Act (such as the Delaney Clause).

While OSHA argues that its statute is different, because of Congress' overriding concern for worker safety and health, the statutory authorities of the FDA, EPA, CPSC and NHTSA also exhibit overriding concern for the safety of the food supply and consumer products, for environmental protection and for traffic safety. Nevertheless, these other agencies have found that estimating the effectiveness of their regulations is consistent with Congressional intent. The experience of other agencies, at the very least, destroys any claim made by OSHA that its unique view is entitled to special deference from the courts.

We shall now summarize the practice of the FDA, EPA,

CPSC and NHTSA in estimating the health benefits of their regulations, in each case also summarizing the pertinent statutory authorities under which these estimations have been made and comparing these authorities to the OSH Act.[14]

Food and Drug Administration

Despite statutory authority which, unlike the OSH Act, on its face would appear to contain no room for risk estimation, the FDA has estimated the magnitude of risk in connection with its regulatory actions. Indeed, the FDA has recently proposed to adopt risk estimation as part of formal Agency policy.

The Delaney Anti-Cancer clause of the Federal Food, Drug and Cosmetic Act, forbids the FDA from approving food additives or animal drugs shown to cause cancer in man or, by appropriate tests, in animals.[15] Both the language and the legislative history of the Delaney Clause demonstrate that Congress thought that cost could not be a consideration justifying carcinogenic food additives. Moreover, the FDA regards the Delaney Clause as a "particularization of the general safety sections of the act." 44 Fed. Reg. 17070, 17074 (March 20, 1979). Thus the FDA interprets its general obligation to disapprove a food additive if the data fails to show that use of the additive "will be safe," [16] as meaning that the additive must be "safe in all

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[14] The following discussion is not, of course, intended to imply endorsement of any particular regulatory decision. Rather, the point is that agencies other than OSHA are making an attempt to estimate risk by some method or another, while OSHA claims that the attempt cannot and should not be made.

[15] 21 U.S.C. §§348(c)(3)(a) (food additives), 376(b)(5)(B) (color additives), and 360b(d)(l)(H) (animal drugs).

[16] Federal Foods, Drug and Cosmetic Act §409(c)(3)(A), 21 U.S.C. §348(c)(3)(a).

respects — including safe from carcinogenicity." 44 Fed. Reg. 17070 at 17074 (March 20, 1979). Cost is not a consideration under these provisions.

Nevertheless, the FDA has found room in this stringent statutory scheme to accommodate the quantitative estimation of the magnitude of risk posed by carcinogenic chemicals. In its proposed regulation of saccharin (which was aborted by special legislation), the FDA estimated "that the lifetime ingestion of the amount of saccharin in one diet beverage per day results in a risk to the individual of somewhere between zero and 4 in 10,000 of developing cancer of the bladder." 42 Fed. Reg. at 20001 (April 15, 1977).

The FDA estimated the number of resulting cancers on the basis of the conservative assumption that "everyone in the United States drank one [diet] beverage a day." *Ibid.* The FDA explained that it did not regard current scientific methods as being capable of determining the "exact risk," but that "techniques are available for estimating the upper limits of the risk." *Ibid.*

Recently the FDA has proposed regulations which would formalize its commitment to quantitative risk estimation. This proposal arises in the context of the provision of the Federal Food, Drug and Cosmetic Act regarding animal drugs. 21 U.S.C. §360b. This provision prohibits approval of a drug which induces cancer in man or animals, unless "no residue" of the drug is found in edible portions of the animal by approved methods of examination. 21 U.S.C. §360b(d)(1)(H). FDA's recent proposal is to approve those methods of examination which are sensitive enough to detect drug residues creating *no more than a one in a million lifetime risk of cancer for the consumer.* 44 Fed. Reg. at 17111 (March 20, 1979 (proposing 21 C.F.R. §§500.89(f), 500.90(a)). The proposed regulations employ the technique of conservative assumptions to avoid understatement of risk in the estimation of whether the one-in-a-million risk is present. Thus the proposed regulations require "linear extrapolation" on the ground that it is "least likely to underestimate risk";[17] they also assume that "the maximum concentration of residues potentially undetected in edible tissues is consumed every day over a lifetime";[18] and they use various other "conservative procedures and assumptions" to help compensate for possible underestimation. 44 Fed. Reg. at 17093 (March 20, 1979).

Another example of FDA action in estimating health risk is found in its proposal of a temporary tolerance for polychlorinated biphenyls (PCB's) in fish. Section 406 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §346, authorizes the FDA to limit the quantity of environmental contaminants in food "to such extent as [it] finds necessary for the protection of public health." In establishing the level of contamination to be tolerated, FDA must take into account "the extent to which the use of such [contaminating] substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected * * *." *Ibid.* In short, the statute is much like the OSH Act, in establishing two criteria for action: 1) health, and 2) feasibility [i.e., the extent to which contamination "cannot be avoided"].

In its recent action reducing the tolerance for PCB's from 5 to 2 ppm, the FDA estimated "the upper limit on the lifetime risk of cancer for heavy consumers of fish most affected by the tolerance" for the three levels suggested by parties to the proceeding: 5 ppm, 2 ppm and 1 ppm. The FDA concluded that the lifetime risk is "9.8 incidences of cancer per 100,000 of the population, assuming the tolerance is 5 ppm; 7.2 per 100,000 assuming the tolerance is 2 ppm; and 4.4 per 100,000 assuming the tolerance is 1 ppm." 44 Fed. Reg. 38330, 38333 (June 29, 1979).

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[17] 44 Fed. Reg. at 17089 (March 20,1979).

[18] 44 Fed. Reg. at 17092 (March 20, 1979).

Because of uncertainties in the data, the FDA stated that the utility of the risk assessment is "extremely limited" and that it did not provide a basis for "precise quantification" of the amount of risk reduction from the reduction in PCB levels. Nevertheless, the FDA concluded that the risk assessment was "illustrative of the toxicological rationale for reducing the tolerance for PCB's in fish." *Ibid.* Moreover, the FDA was able to conclude that for average consumers, the additional health protection in moving from 2 ppm to 1 ppm (as some parties to the proceeding had urged) would be "slight" and would thus not justify the significantly greater impact that such a tolerance would have on food availability (estimated to be approximately $16 million). 44 Fed Reg. 38330 at 38335, 38333 (June 29, 1979).

In short, under a statute much like the OSH Act, the FDA concluded that although its "paramount concern" is "protection of the public health," it must nevertheless "ensure that the direct economic consequences of the tolerance (in this case, decreased sales and employment in the commercial fishing industry) will not be disproportionate to the increased degree of public health protection accomplished by the tolerance." 44 Fed. Reg. 38333, 38334 (June 29, 1979). Pursuant to that responsibility, the FDA performed a quantitative estimation of the degree of public health benefit from the various proposed levels of regulation, and while recognizing the uncertainties inherent in the estimation, nevertheless utilized it in arriving at its final judgment as to the proper level of regulation.

Environmental Protection Agency

EPA's practice with respect to suspected carcinogens is set forth in "Health Risk and Economic Impact Assessments of Suspected Carcinogens: Interim Procedures and Guidelines," 41 Fed. Reg. 21402 (May 25, 1976). This document requires that where EPA proposes to take regulatory action against a suspected carcinogen, a "risk analysis" shall be performed, which will estimate "excess lifetime incidence, or average excess cancer rates * * *." *Id.*, at 21405. The document provides that "[t]he uncertainty in the data and extrapolation techniques should be clearly indicated." *Ibid.* In addition, EPA points out that "the risk estimates should be regarded only as rough indications of effect." *Id.*, at 21404. Nevertheless, EPA's policy is to perform these risk estimates where this is consistent with its statutory authorities.

The EPA experience confirms 1) that risk estimation for carcinogens, while concededly not a precise science, is nevertheless sufficiently reliable for regulatory purposes if used with an appreciation of its limitations, and 2) that the statutory concepts of "safety" and "feasibility" are consistent with the use of risk estimation as an element in the regulation of suspected carcinogens.

Under the Safe Drinking Water Act, 42 U.S.C. §300f et seq., EPA has authority to set "national interim primary drinking water regulations." These regulations are required to "protect health to the extent feasible, using technology * * * which the Administrator determines [is] generally available (taking costs into consideration) * * *." §1412(a (2), 42 U.S.C. §300g-1(a)(2). Like the OSH Act, the overriding purpose of the Safe Drinking Water Act is to protect health but with some allowance for feasibility.[19]

EPA has proposed regulations governing the concentrations of trihalomethanes in drinking water, on the basis of a suspected cancer risk. 43 Fed. Reg. 5756 (Feb. 9, 1978). These regulations were proposed at a level which EPA determined to be "as low as economically and technologically feasible." 43 Fed. Reg. 5763. However, because the proposed regulations would require very substantial expenditures (annual expenditures, including capital charges,

[19] H.R. Rep. No. 93-1185, 93rd Cong. 2d Sess. at 9.

operation and maintenance, of between $57 and $145 million), EPA also estimated the extent of the cancer risk presented by trihalomethanes in drinking water. EPA concluded that "a statistical extrapolation of the data indicates that a life-long exposure to those contaminants in drinking water may account for 200 excess fatalities per year nationwide. * * *. Other studies would indicate even higher risks." 43 Fed. Reg. at 5769.

EPA's estimates were obtained from a report of the National Academy of Sciences, which "suggested that the risk could be approximated with available extrapolation techniques and, applying such techniques, derived risk estimates for the identified carcinogens." 43 Fed. Reg. at 5768. Referring to the Academy's report, EPA stated that although "it is not possible to project with accuracy from risk estimates to absolute numbers of cancers in a human population", nevertheless the "approximate impact" of the standard had been estimated. 43 Fed. Reg. at 5761.

Section 303 of the Clean Water Act, 33 U.S.C. §1313, requires the States to establish water quality standards subject to EPA review and approval. Under section 303, EPA has also performed risk estimates for carcinogens.

Section 303 provides that water quality standards must "protect the public health or welfare, enhance the quality of the water and serve the purposes of the Act." §303(c)(2), 33 U.S.C. §1313(c)(2). EPA is required to establish "water quality criteria", which reflect "the kind and extent of all identifiable effects on health" which may be expected from the presence of pollutants in the water. Clean Water Act, §304(a), 33 U.S.C. §1314(a). A standard is then set for a particular body of water depending on the use anticipated; if the anticipated use involves human use of the water (drinking, recreation or eating fish from the water), then the standard must be set to "protect the public health" (§303(c (2)), taking into account the "water quality criteria."

In a recent notice, EPA has proposed water quality criteria designed to assist in the process of setting water quality standards. 44 Fed. Reg. 15926 (March 15, 1979). In the case of carcinogenic water pollutants, the EPA criteria "estimate ambient water concentrations which * * * represent various levels of incremental cancer risk." 44 Fed. Reg. at 15929.

In the case of benzene, EPA stated that "the recommended concentration of benzene in water for maximum protection of human health is zero." 44 Fed. Reg. at 15936. However, "[b]ecause attaining a zero concentration level may be infeasible in some cases and in order to assist the Agency and States in the posible future development of water quality regulations," EPA estimated "the concentrations of benzene corresponding to several incremental lifetime cancer risk levels." *Ibid.* Specifically, EPA estimated the concentrations of benzene which would pose a lifetime risk to persons drinking the water and eating fish taken from the water of one in 100,000, one in one million, and one in ten million. *Ibid.*

The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) provides that a pesticide may not be registered if its use will result in "unreasonable adverse effects on the environment", a phrase that is defined as "any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide." 7 U.S.C. §§136(bb), 136a(c)(5), 136d(b).

EPA's present practice in the pesticide area is illustrated by its recent actions in the cases of the pesticides amitraz and chlorobenzilate.

EPA concluded that the use of amitraz on pears and apples "might pose a very small risk of cancer to certain exposed groups." 44 Fed. Reg. 2678 (January 12, 1979). It further concluded that there is "an indication of possible

significant benefit from the use of amitraz on pears" but "little or no benefit from its use on apples." *Ibid.* Accordingly, EPA granted a conditional registration for pears (on the basis of "substantial benefits and very small risks") and denied registration as to apples. 44 Fed. Reg. 32736 (June 7, 1979).

In reaching this decision, EPA estimated the lifetime risks for individuals consuming amitraz-treated apples and pears (two chances in a million) and the lifetime cancer risks for workers applying amitraz to pears and apples (one in ten thousand for apples, six in one hundred thousand to one in ten thousand for pears). 44 Fed. Reg. at 2681.

Commenting on these risk estimations, EPA stated that they are "neither scientific certainties nor absolute upper limits, but are used by the Agency only as rough approximations of potential health risks." *Ibid.*

EPA recently decided to cancel the registration of chlorobenzilate for uses other than citrus uses in certain states; as to these citrus uses, registration was allowed subject to restrictions on handling of the pesticide. 44 Fed. Reg. 9548 (Feb. 13, 1979). In balancing the risks and benefits, EPA estimated the magnitude of the lifetime cancer risk through dietary exposure in Florida and in the rest of the United States (the estimated risk ranges from 0.5 to 7.0 in a million). 44 Fed. Reg. at 9556, 9557.

During the proceedings leading to EPA's decision, an environmental organization had criticized the cancer risk assessment on the ground that it did not take into account the heterogeneity of the human population, and possible synergistic effects of chlorobenzilate with other chemicals in the environment. EPA's response was that it would use the "conservative assumption" technique to avoid underestimation resulting from these uncertainties:

> Because uncertainties such as synergism and heterogeneity exist, the Agency used the most conservative model and test results from the most sensitive group of test animals to extrapolate to humans the cancer risk associated with chlorobenzilate.

44 Fed. Reg. at 9553.

EPA also has the authority to establish limits on radiation exposures outside the boundaries of nuclear facilities. Reorganization Plan No. 3, 1970, §2(5). These standards are authorized by the Atomic Energy Act, which requires these standards to "protect health or to minimize danger to life or property." 42 U.S.C. §2201(b). This language has been interpreted by the Nuclear Regulatory Commission and by EPA to require risk-benefit balancing in the establishment of radiation protection standards. See 10 C.F.R. §20.1(c) (NRC interpretation); 40 Fed. Reg. 23420, 23421 (May 29, 1975) (EPA interpretation).

In proposing its environmental radiation standards, EPA calculated the expected health benefits and the costs, estimating "the cost of implementing the proposed standards for these long-lived radioactive materials to be less than $100,000 per potential case of cancer, leukemia, or serious genetic effect averted." 40 Fed. Reg. at 23422. In the final regulation, which adopted the protection levels proposed, EPA rejected criticisms that its risk estimates were either too low or too high. In particular, EPA stated that "the weight of currently available scientific evidence supports the continued use of a linear, nonthreshold model for deriving standards to protect public health." 42 Fed. Reg. 2858, 2859 (Jan. 13, 1977) (promulgating 40 C.F.R. Part 190).

Consumer Product Safety Commission

The CPSC operates under a statutory mandate to protect the consumer from "unreasonable risks of injury" associated with consumer products. 15 U.S.C. §2051(b)(1). Each standard must be "reasonably necessary" to prevent

or reduce such risk. 15 U.S.C. §2056(a). This compares to the OSH Act, which is aimed at "material" impairment of health and requires that standards be "feasible" and "reasonably necessary." 29 U.S.C. §§652(8), 655(b)(5).

The CPSC's recent standard for walk-behind power lawn mowers illustrates its use of risk estimation in complying with its statutory mandate. In this standard, the CPSC estimates that about 150,000 injuries associated with power lawn mowers occur each year, about 60,000 of which are treated in emergency rooms. 44 Fed. Reg. at 9992 (Fed. 15, 1979). The CPSC further breaks down the number of injuries expected to be saved by each of the major requirements of the standard; estimates the dollar savings exclusive of pain and suffering; estimates the total retail price increase resulting from the standard ($189 million); and concludes that the standard is reasonably necessary to reduce an unreasonable risk of injury. 44 Fed. Reg. at 9996-7 (Feb. 15, 1979).

The CPSC also has authority under the Federal Hazardous Substances Act to ban "hazardous substances", defined as substances which "may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children." 15 U.S.C. §1261(f)(1)(A). In its notice declaring tris — a chemical used as a flame retardant in children's sleepwear — to be a banned hazardous substance, the CPSC relied on three risk assessments concerning the potential of tris to cause cancer. 42 Fed. Reg. 18850, 18851 (April 8, 1977). These estimates were prepared by the Commission's Bureau of Biomedical Science, by the Environmental Defense Fund, and by researchers at the Department of Biochemistry at Berkeley. The Bureau's high estimate was 5100 cases per million male children exposed. The highest estimate (from Berkeley) was 17,000 cases per

million children exposed. *Ibid.* In view of the very high range of risk estimates, the Commission took emergency action.

National Highway Traffic Safety Administration (NHTSA)

In its "Five Year Plan for Motor Vehicle Safety and Fuel Economy Rulemaking", NHTSA has stated that among the factors it considers in establishing motor vehicle safety standards are "anticipated costs to consumers and industry" and "lifesaving potential of a safety standard." 43 Fed. Reg. 11100, 11101 (March 16, 1978). An excellent example of NHTSA's practice in this regard is found in its air bag standard, which sets forth the "Fatalities Prevented Per Year" and the "Injuries Prevented Per Year" under each of the various occupant restraint systems under consideration, with cost estimates for the full front air bag system (one of the options chosen in the final regulation). 42 Fed. Reg. 34289, 34298-99 (July 5, 1977).[20]

NHTSA's statutory mandate is similar to OSHA's. Like OSHA, NHTSA's overriding mission is to protect health and safety: to "reduce traffic accidents and deaths and injuries to persons resulting from traffic accidents." 15 U.S.C. §1381. However, the standards must be "reasonable, practicable and appropriate." 15 U.S.C. §§1392(f), 1391(2). Judge Stevens' description of NHTSA's authority fits almost exactly to OSHA:

> Although I recognize that safety is the 'overriding consideration in the issuance of standards' under this Act, the statute requires respondent to consider

[20] A more detailed breakdown of NHTSA's cost-benefit analysis of the air bag standard is set forth at 41 Fed. Reg. 31860 (July 30, 1976). Using the highest NHTSA cost estimate, the full front air cushion system, adopted in the final regulation, is estimated to save lives at a cost just under $300,000 per life (leaving out of the estimate any allocation of cost to the substantial number of injuries prevented by the regulation).

whether a proposed standard is 'reasonable, practicable and appropriate' before it is prescribed.

H & H Tire Company v. Department of Transportation, 471 F.2d 350, 357 (7th Cir. 1972) (Stevens, J., concurring). But unlike OSHA, NHTSA interprets this mandate to require it to estimate the health and safety benefits of its regulations.

CONCLUSION

Because OSHA has refused to estimate the expected health benefits for the benzene standard, the judgment of the Court of Appeals setting the standard aside should be affirmed.

Respectfully submitted,

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1979

No. 78-911

INDUSTRIAL UNION DEPARTMENT, AFL-CIO, *Petitioner,*

v.

AMERICAN PETROLEUM INSTITUTE, *et al., Respondents.*

No. 78-1036

RAY MARSHALL, SECRETARY OF LABOR, *Petitioner,*

v.

AMERICAN PETROLEUM INSTITUTE, *et al., Respondents.*

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

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BRIEF OF THE CAPITAL LEGAL FOUNDATION AS AMICUS CURIAE

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1979

No. 78-911

INDUSTRIAL UNION DEPARTMENT, AFL-CIO, *Petitioner,*

v.

AMERICAN PETROLEUM INSTITUTE, *et al., Respondents.*

No. 78-1036

RAY MARSHALL, SECRETARY OF LABOR, *Petitioner,*

v.

AMERICAN PETROLEUM INSTITUTE, *et al., Respondents.*

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

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BRIEF OF THE CAPITAL LEGAL FOUNDATION AS AMICUS CURIAE

INTEREST OF *AMICUS CURIAE* CAPITAL LEGAL FOUNDATION

The Capital Legal Foundation is a tax exempt, non-profit organization located in Washington, D.C. It was organized in 1977 to engage in non-partisan legal research, study and analysis for the benefit of the general public as to the effect of developing concepts of law on the nation's democratic institutions. The Foundation was also organized to provide legal representation, and

to assist other organizations in providing such representation, on matters of public interest at all levels of the judicial process. In pursuit of these objectives, the Foundation closely monitors the development of important regulatory actions by federal agencies, and participates in related litigation.

The Foundation believes that the failure of the Secretary of Labor to determine the benefits of the standard under review must not be condoned by this Court. In our brief, we show that the Secretary's determinations under the Occupational Safety and Health Act of 1970 ("the Act") are subject to judicial review under the substantial evidence test, since that standard is commanded by Section 6(f) of the Act and the pertinent legislative history. We then show that the Secretary's action was contrary to the Act, which requires, *inter alia,* that safety and health standards be based on the "best available evidence" and the "latest available scientific data in the field." Proven analytical techniques could have been utilized to yield objective and reliable evidence about the ultimate worth of the standard, which the Secretary chose to ignore. We also show that even if a test less severe than the substantial evidence test is applied, the Secretary's action must be set aside, because it was irrational for the Secretary to promulgate a fabulously expensive standard without the slightest notion of the benefits to be derived.

We also demonstrate that as the record shows, the Secretary could have estimated the benefits of the benzene standard. We further suggest that important public policy objectives would be served by compelling such an analysis. The Foundation is concerned that this Court's condonation of the Secretary's approach to the instant standard would be interpreted by the Secretary

and other comparable federal risk regulators as a license to ignore considerations militating against regulatory actions they may propose. Such a decision would also diminish the incentive of those administrators to ensure that the best available analytical techniques are brought to bear upon the complex technological issues that confront them. The public's interest in the sound and reasonable administration of federal health and environmental legislation would be ill-served by such a result.

Owing allegiance to no interest other than that of the general public, the Capital Legal Foundation respectfully submits this brief as *Amicus Curiae.* All parties have consented to the filing of this brief. Copies of the letters of consent are filed with this brief.

STATEMENT OF THE CASE

The Capital Legal Foundation adopts the Statement of the Case contained in the brief of the Respondents.

SUMMARY OF ARGUMENT

I.

In certain cases, this Court has disregarded the language of a statute because poor draftsmanship or a legislative compromise produced ambiguities, or because the Court believed that a literal interpretation would compromise the statute's purposes. *E.g., United Steelworkers of America, AFL-CIO-CLC* v. *Weber,* 47 U.S.L.W. 4851, 4857 (June 27, 1979). In the instant case, the Court is presented with no such difficulty in construing the provisions of the Occupational Safety and Health Act of 1970 governing judicial review of safety and health standards. Section 6(f) of the

Act states plainly that judicial review of all of the Secretary's determinations in promulgating a standard is under the substantial evidence test. The legislative history confirms this conclusion, and reveals that the enactment of the substantial evidence test in Section 6(f) was the result of a legislative compromise which was important to the passage of the Act. See *Associated Industries of New York State, Inc.* v. *United States Dep't of Labor*, 487 F.2d 342, 348 (2d Cir. 1973). The purposes of the Act would not be adversely affected if the substantial evidence test is applied. Thus, there is no occasion for this Court to disregard the plain terms of the Act, and judicial review of the Secretary's benzene standard is therefore under the substantial evidence test.

II.

In promulgating the benzene standard, the Secretary decided not to prepare an estimate of the benefits to be derived from the standard. He concluded that it would be impossible to prepare such an estimate, assertedly because there is no known dose-response curve for benzene. The Secretary contends that his decision not to estimate the benefits of the standard is a "policy" judgment which the Act entitles him to make, and he argues at least implicitly that such "policy" judgments are subject to judicial review under the less exacting "arbitrary and capricious" test.

Regardless of the standard of judicial review that is applied, the Secretary's action was unlawful. As the Court below found, contrary to the Secretary's assertion, a rough but educated estimate of the benefits of the standard could have been performed, and preliminary estimates of a dose-response curve for benzene are ap-

parently already available. The Secretary's judgment that it would be impossible to prepare such an estimate is therefore unsupported by substantial evidence. Also, the Act, its legislative history, and the decisions of courts which have considered the issue all leave no doubt that the benefits of a standard are a factor which the Secretary must consider in detail. See, e.g., *RMI Co.* v. *Secretary of Labor and OSAHRC*, 594 F.2d 566 (6th Cir. 1979); *Turner Co.* v. *Secretary of Labor*, 561 F.2d 82 (7th Cir. 1977). Therefore, by refusing to perform the estimate, the Secretary violated the requirements of the Act which command, *inter alia*, that he regulate on the basis of the "best available evidence" and the "latest available scientific data in the field." Section 6(b)(5), 29 U.S.C. § 655(b)(5). Further, by ignoring the benefits of the standard, the Secretary did not consider a factor which was obviously relevant to the issues before him. His decision was consequently irrational, and therefore "arbitrary and capricious", in the traditional administrative law sense. *Citizens to Preserve Overton Park* v. *Volpe*, 401 U.S. 402 (1971).

Finally, while refusing to perform an analysis of the benefits of the standard, the Secretary declared that the benefits "may be appreciable." As the Court below found, the Secretary's statement was based on the assumption that exposure to lower levels of carcinogens is safer than exposure to higher levels. The Court below properly concluded that while there may be "some" evidence to support this proposition, there is hardly the substantial evidence required by the Act. This is especially true since, as noted above, additional information about the benefits of the standard was readily available to the Secretary. Indeed, during

the underlying rulemaking proceedings, both the Council on Wage and Price Stability and the Department of Health, Education and Welfare informed OSHA that such an estimate could, and should, be performed.

In sum, under any applicable standard of review, the Secretary's failure to estimate the benefits of the standard was unlawful.

III.

Important policy objectives would be served if the Secretary is required to estimate the benefits of standards he promulgates. First, such a result would contribute to assuring a full inquiry by the Secretary into the issues that confront him, thus strengthening OSHA rulemaking procedures. Second, such a requirement would assure that the value judgments implicit in the Secretary's choices are made explicit, thus increasing public acceptance of and confidence in his determinations. On this subject, we believe that the Secretary's reluctance to admit that the choices he must make involve evaluation of monetary considerations and human value judgments reflects an immature approach to risk regulation. In regulations such as the instant one, reconciliation of these competing interests is inevitable. See Handler, *A Rebuttal, the Need For a Sufficient Scientific Base for Government Regulation,* 45 Geo. Wash. L. Rev. 808 (1975). Third, a requirement that the Secretary consider the benefits of a standard will help overcome the inevitable institutional bias which regulators often develop in favor of their own regulatory proposals. See *Sierra Club* v. *Froehlke,* 486 F.2d 946, 950 (5th Cir. 1973). Finally, to compel the Secretary to make such an analysis may have the salutary effect of causing him to improve the quality of his policy analysis staff, which the record reveals is poorly regarded by experts in the field. *See, e.g.,* Appendix at 140, 141 (testimony of Dr. Richard Zeckhauser).

Contrary to the implication inherent in the Government's brief, an analysis of the benefits of the standard would not necessarily have required precise incremental quantification of those benefits. Less precise estimates could have been performed, and would have been useful to the Secretary. This does not mean, however, that quantification of benefits should not be attempted where it is possible. Indeed, quantification would contribute to objectivity, and should be established as a regulatory goal.

Finally, it should be emphasized that the issue here is a narrow one. The question is not whether the Secretary's final choices gave too much consideration to costs or benefits in the standard under review. This record does not permit the Court to make that assessment, since the Secretary did not estimate the benefits in the first place. The only question here is whether the estimate of benefits was required to be performed.

IV.

To condone the Secretary's failure to estimate the benefits of the instant standard would be to sanction conduct violative of the Act and irrational under any sensible standard of review. Also, such a decision would surely be interpreted by the Secretary and by other comparable federal risk regulators as a license to bring less than the best available analytical techniques to bear upon the complex issues that confront them. This would weaken the administrative process

upon which the society heavily depends to resolve many such complex technological issues. Such an outcome would ill-serve the public interest. Accordingly, the judgment of the Court below should be affirmed.

ARGUMENT

I. The Act Commands Judicial Review of the Secretary's Determinations Under the Substantial Evidence Test

This Court "[o]ften [has] difficulty interpreting statutes either because of imprecise drafting or because legislative compromises have produced genuine ambiguities." [1] On other occasions, the Court has disregarded the literal language of a statute because the Court believed that a literal interpretation "would 'bring about an end completely at variance with the purpose of the statute.' " [2] In these latter cases, the Court has examined the legislative history and the historical background of the statute to discern the true purpose of the Congress, on the ground that " 'a thing may be within the letter of the statute and yet not within the statute, because not within its spirit, nor within the intention of its makers.' " [3]

With respect to the scope of judicial review of the Secretary's determinations in the instant case, the Court is presented with none of these dilemmas. The language of the statute is clear, and it accurately reflects a legislative compromise which was important to the passage of the Act.[4] Indeed, to give literal effect to the language of the Act would be finally to vindicate the stated intent of Congress. Moreover, such an interpretation would not adversely affect the purposes of the Act.

The Act is unusual in that "it does not depend upon reference to the Administrative Procedure Act for specification of the procedures to be followed" in the development of OSHA standards, or the scope of judicial review.[5] Rather, the scope of review is governed by Section 6(f) of the Act, 29 U.S.C. § 655(f), which provides:

> Any person who may be adversely affected by a standard issued under this section may at any time prior to the sixtieth day after such standard is promulgated file a petition challenging the validity of such standard with the United States Court of Appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such standard. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary. The filing of such petition shall not, unless otherwise ordered by the court, operate as a stay of the standard. *The determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole* (emphasis added).

The plain language of Section 6(f) leaves no doubt that the "determinations" to which it applies the sub-

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[1] *United Steelworkers of America, AFL-CIO-CLC* v. *Weber*, 47 U.S.L.W. 4851, 4857 (June 27, 1979) (Burger, C.J., dissenting).

[2] *Id.* at 4853, quoting *United States* v. *Public Utilities Comm'n*, 345 U.S. 295, 315 (1953).

[3] *Id.* at 4853, quoting *Holy Trinity Church* v. *United States*, 143 U.S. 457, 459 (1892).

[4] The Occupational Safety and Health Act of 1970, 29 U.S.C. § 651 et seq. (hereinafter cited as "the Act").

[5] *Industrial Union Dep't, AFL-CIO* v. *Hodgson*, 499 F.2d 467, 472 (D.C. Cir. 1974).)

stantial evidence test refers to all of the Secretary's decisions in promulgating a safety or health standard, "includ[ing] the overall *policy* decision to promulgate a rule." "The word 'determinations' is used throughout § 655 to include policy choices as well as factual findings, and particularly to include promulgation of standards." [6] Thus, the Act makes it clear that judicial review of the standard here in question must be under the substantial evidence test.

The legislative history of the Act confirms that the substantial evidence test is to be applied to the Secretary's determinations. The OSHA bill as enacted by the Senate provided for the informal rulemaking procedures which were contained in the bill as ultimately enacted. However, the Senate version was silent on the scope of judicial review. The House-passed bill would have required formal rulemaking procedures on the record in accordance with 5 U.S.C. §§ 556 and 557. In conference, the Senate version was adopted with respect to judicial review. The "tradeoff" made by the conferees was that the House would recede from its insistence upon formal rulemaking on the record dur-

[6] *Associated Industries of New York State, Inc.* v. *United States Dep't. of Labor*, 487 F.2d 342, 348 (2d Cir. 1973) (emphasis added).

See, e.g., Section 6(b)(1), 29 U.S.C. § 655(b)(1) ("Whenever the Secretary . . . *determines* that a rule should be promulgated . . .") (emphasis added); Section 6(b)(2), 29 U.S.C. § 655(b)(2) ("Where an advisory committee is appointed and the Secretary *determines* that a rule should be issued, he shall publish the proposed rule . . .") (emphasis added); Section 6(b)(4), 29 U.S.C. § 655(b)(4) (the Secretary shall either issue a rule "or make a *determination*" that one will not be issued) (emphasis added); Section 6(g), 29 U.S.C. §655(g) ("In *determining* the priority for establishing standards under this section, the Secretary shall give due regard" to the enumerated factors) (emphasis added).

ing the hearing stage in return for the Senate's agreement to the substantial evidence test upon judicial review of the promulgated rule.[7]

That this is precisely what Congress intended is confirmed by the statements of Representative Steiger, one of the Act's sponsors, during the floor debate in the House on the conference report. Thus, in urging his House colleagues to accept the compromise, Representative Steiger noted that the conference bill contained several items which the House had originally insisted upon, including "the test for judicial review of standards." [8] Later in the debate, Representative Steiger underscored his understanding that the substantial evidence test would be applied:

> The Secretary's standard will *only* be sustained by the courts if it is supported by substantial evidence of the record considered as a whole. Thus, the Secretary must have a record upon which to base his findings and serve as the basis for judicial review * * * * [T]he Court review based upon substantial evidence provides a sufficient element of fairness to satisfy me that the conference report should be adopted.[9]

Given the unequivocal language of the statute which accurately reflects an important legislative compromise, it is clear that the standard of judicial review of all of the Secretary's determinations in promulgating

[7] See Subcomm. on Labor of the Senate Comm. on Labor and Public Welfare, 92d Cong., 1st Sess., Legislative History of the Occupational Safety and Health Act of 1970, 1201, 147, 1187 (Comm. Print 1971) (hereinafter cited at "Leg. Hist.").

[8] Leg. Hist. 1212.

[9] Leg. Hist. 1218 (Emphasis added).

standards, including so-called "policy" determinations, is the substantial evidence test.[10]

II. The Secretary's Failure To Estimate the Benefits of the Benzene Standard Is Unlawful Also. His Finding That Benefits "May Be Appreciable" Is Not Supported by Substantial Evidence

A. The findings of the Court below

The Fifth Circuit found that the Secretary did not even "attempt . . . to measure the extent to which the

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[10] *Associated Industries of New York State Inc.* v. *United States Dep't of Labor, supra; Florida Peach Growers Ass'n* v. *United States Dep't of Labor,* 489 F.2d 120, 128, n.13, (5th Cir. 1974). But see *Industrial Union Dep't, AFL-CIO* v. *Hodgson, supra.* In *IUD,* which is the seminal case on this point, the D.C. Circuit held that certain of the Secretary's determinations may be "on the frontier of scientific knowledge," and therefore not susceptible of factual support. The Court therefore concluded that as to such policy judgments, "the court's approach must necessarily be different no matter how the standards of review are labeled [by Congress]." 499 F.2d at 475. Accord: *Society of the Plastics Industry, Inc.* v. *OSHA,* 509 F.2d 1301 (2d Cir. 1975); *American Iron & Steel Institute* v. *OSHA,* 577 F.2d 825 (3d Cir. 1978).

We submit that reviewing courts are not free to disregard the clear statutory language and legislative intent, and substitute their own notions of proper judicial review. The Secretary will not be prevented from accomplishing his statutory purposes if the substantial evidence test is applied, for it will be the rare case indeed in which there will be literally no evidence bearing upon a "policy" matter before him. This case provides a perfect example; as we discuss more fully *infra,* the Secretary claimed that it was impossible to estimate the benefits of the benzene standard, because there assertedly is no known dose-response curve for benzene. However, the Court below found that preliminary estimates of a dose-response curve are already being made. In any event, Section 6(b)(5) of the Act embodies Congress' recognition that perfect and complete evidence will not always be available, and it accordingly permits the Secretary to regulate on the flexible bases of the "the best available evidence," "research, demonstrations and experiments," and "the latest available scientific data in the field." 29 U.S.C. § 655(b)(5).

leukemia hazard of benzene exposure would be reduced by lowering the permissible exposure limit from 10 ppm to 1 ppm."[11] Rather, the Secretary merely assumed that the benefits from such a reduction "may be appreciable." He "based this assumption on a finding that benzene was unsafe at any level, and that exposures to lower levels of toxic materials would be safer than exposures to higher levels."[12] The Court concluded that this "assumption" did not satisfy the requirements of the Act.

The Secretary contended that "risk quantification at low exposure levels and therefore estimates or expected benefits from the standard cannot presently be made . . ."[13] The Court held that while an elaborate, cost-benefit analysis of the standard could not be made,[14] the Secretary could, and should, have made a "rough but educated estimate . . . of the extent of benefits expected from reducing the permissible exposure level from 10 ppm to 1 ppm."[15]

The Secretary contends that his decision not to estimate the benefits of the benzene standard was a policy choice which he was licensed to make under the Act. The implication is that this decision is subject to review under the "arbitrary and capricious" test which courts like the D.C. Circuit in *Industrial Union*

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[11] *American Petroleum Institute, et al.* v. *OSHA,* 581 F.2d 493, 503 (5th Cir. 1978).

[12] *Id.*

[13] *Id.* at 504 n.23.

[14] *Id.*

[15] *Id.* at 504.

Dep't, AFL-CIO v. *Hodgson* would apply to policy judgments.

In determining whether administrative action has been arbitrary or capricious, a court must determine, *inter alia*, whether "the decision was based on a consideration of the relevant factors . . ."[16] Where, as here, the administrative action (or omission) relates directly to a major judgment involving competition among conflicting interests, the Court must examine it with care.[17]

In the remainder of Section II of this brief, we demonstrate that detailed consideration of the benefits of the standard is mandated by the plain terms of the Act, and by the crucial portions of its legislative history. We also show that the record supports the conclusion that the Secretary could, in fact, have produced at least a "rough but educated estimate" of the benefits of the standard, and that his failure to do so was therefore unsupported by substantial evidence. Even if the "arbitrary and capricious" test is applied, the Secretary fails, because his "policy" decision not to estimate benefits ignored a factor which he was mandated to consider under the Act. Finally, we demonstrate that the Secretary's declaration that benefits "may be appreciable" was, as the Court below found,

[16] *Citizens to Preserve Overton Park* v. *Volpe*, 401 U.S. 402, 416 (1971); *Bowman Transp., Inc.* v. *Arkansas Best Freight Systems*, 419 U.S. 281, 285 (1974).

[17] *American Shipbuilding Co.* v. *N.L.R.B.*, 380 U.S. 300, 318 (1965); *N.L.R.B.* v. *Brown*, 380 U.S. 278 (1965); *Matson Navigation* v. *Connor*, 258 F. Supp. 144 (N.D. Cal. 1966), aff'd 394 F.2d 514 (9th Cir. 1968), cert. denied 393 U.S. 998.

based on an assumption, and not supported by substantial evidence on the record considered as a whole.[18]

B. The language of the Act

The provisions of the Act governing the promulgation of safety and health standards leave no doubt that the Secretary cannot ignore the question of the benefits those standards will generate in terms of increased employee protection. It is a matter plainly relevant to his determinations, for the statute does not authorize the Secretary to seek absolute protection of employee safety and health. Rather, the Act speaks in relative terms throughout, and commands the Secretary to consider a variety of factors in promulgating standards.

Thus, Section 2(b) states that the purpose of the Act is "to assure *so far as possible* every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources." 29 U.S.C. § 651(b) (emphasis added). Obviously, if the Secretary is to assure that the nation's finite resources for promoting occupational safety and health are allocated so as to offer protection from as many hazards as possible,[19] and not just the one which happens

[18] We wish to emphasize that the issue presented in this case is a narrow one. The question is now how the relative costs and benefits of a standard should be reconciled under the Act. That question cannot be answered on this record since the Secretary has provided no estimate of benefits in the first place. The only question here is whether the Secretary should have made such an estimate. A decision on the proper influence of costs and benefits upon the Secretary's final choices under the Act must await a case in which the requisite factual predicates are present.

[19] The Occupational Safety and Health Review Commission ("OSHRC") has recognized that "employers have finite resources

to occupy the Secretary's attention at the moment, common sense tells us that the Secretary must consider what, if any, benefit will be derived from the expenditure of enormous sums to combat just one of those hazards.

Next, Section 3(8) of the Act states that the standards promulgated by the Secretary can only establish "conditions . . . practices, means, methods, operations, or processes, *reasonably necessary* or appropriate to provide safe or healthful employment and places of employment." 29 U.S.C. § 652(b) (emphasis added). Again we see that Congress mandated consideration of the reasonableness of standards which the Secretary would adopt.

Section 6(b)(5) of the Act, 29 U.S.C. § 655(b)(5), provides:

> The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, *on the basis of the best available evidence,* that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, *other considerations*

available for use to abate health hazards." *Continental Can Co.*, 4 BNA OSHC 1541, 1547, 1976-77 CCH OSHD ¶ 21,009 at 24,256 (1976).

> *shall be the latest available scientific data in the field,* the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of *objective criteria* and of the performance desired (emphasis added).

Here we see that contrary to the position of the Secretary, the question whether an employee "will suffer material impairment of health or functional capacity" is not the only relevant concern in promulgating standards governing exposure to toxic materials or harmful physical agents. The Secretary must consider "the best available evidence," and he "*shall* [consider] the latest available scientific data in the field . . ." (emphasis added). Also, "[w]henever practicable," standards must be expressed "in terms of objective criteria." The obvious implication of this Congressional command is that the process of setting standards must be as objective as practicable. Subjective determinations are unlikely to result in standards which permit evaluation of an employer's performance in objective terms.

In sum, the language of the statute makes it clear that Congress required objective consideration of that which is "possible" and "reasonable." The terms of the Act also leave no doubt that the Secretary simply is not free to disregard the "best available evidence" and the "latest available scientific data in the field". By ignoring available analytical techniques which would have yielded such evidence and data, the Secretary acted irrationally, and he violated these clear statutory requirements.

C. The key legislative history

That the Act was intended by Congress to insure that the Secretary would consider the measure of benefits to be derived from a standard is also clear from the critical portions of the legislative history. The provision of the Act relied upon most heavily by the Secretary, i.e., the requirement that standards be "feasible," was the product of an amendment authored by Senator Javits. The bill he sponsored (S. 2788) defined feasibility for the purpose of standards as including the "technical feasibility, reasonableness, and practicality" of the standard.[20] Senator Javits' bill was not accepted, but the term "feasibility" was included in the bill reported out by the Senate Committee. Senator Javits explained the purpose of his amendment as follows:

> As a result of this amendment the Secretary, in setting standards, is expressly required to consider feasibility of proposed standards. This is an improvement over the Daniels bill, which might be interpreted to require absolute health and safety in all cases, regardless of feasibility, and the Administration bill, which contains no criteria for standards at all. Leg. Hist. 58.[21]

[20] S.2788 § 4(c); Leg. Hist. 38-39.

[21] Interestingly, in commenting on the Senate Committee's bill, Senator Javits stated that based on the history of the Department of Labor's enforcement of safety and health standards, "labor has little reason to expect, or business any reason to fear, overly energetic administration of this Act by the Secretary of Labor or disregard by him of the legitimate concerns of business." Leg. Hist. 55. Even given these expectations, the Senator insisted on an amendment which made it plain that the Secretary is not to seek absolute health protection. Had Senator Javits anticipated that the Secretary would disregard considerations which might militate against regulatory action which he proposed, as the Secretary has done here, perhaps the Senator would have sought even more explicit restraints on the Secretary's power. In any event, it is clear that the disregard for opposing views which the Secretary has exhibited in this case is not what the Senator desired, or expected.

Later, when the Senate Committee bill was being considered by the full Senate, Senator Dominick was concerned that the effect of Senator Javits' amendment had been diluted. Senator Dominick was concerned that the first sentence of Section 6(b)(5) as reported [22]

> could be read to require the Secretary to ban all occupations in which there remain some risk of injury, impaired health or life expectancy. In the case of all occupations, it will be impossible to eliminate all risks to safety and health. Thus, the present criteria could, if literally applied, close every business in this nation. In addition, in many cases, *the standard which most 'adequately' and 'feasibly' assures the elimination of the danger would be the prohibition of the occupation itself.* Leg. Hist. 367 (emphasis supplied in part, added in part).

Ultimately, Senator Dominick introduced an amendment to the first sentence of Section 6(b)(5) which was adopted without objection, and which was included in the bill as enacted. The amendment injected the phrase "dealing with toxic or harmful physical agents," thus clarifying that the first sentence of Section 6(b)(5) applies only to occupational safety and health standards. The amendment also injected the phrase "to the extent feasible," thus establishing feasibility

[22] Section 6(b)(5) of S.2193 as reported provided:

> The Secretary in promulgating standards under this subsection, shall set the standard which most *adequately and feasibly assures,* on the basis of the best available evidence, that no employee will suffer *any* impairment of health or functional capacity, or diminished life expectance even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Leg. Hist. 242 (emphasis added).

as an express limitation on the Secretary's obligation to "adequately" assure that employees would not be materially impaired. Finally, the word "material" was substituted for the word "any" in describing the level of impairment which the Secretary should strive to prevent. That this change was intended to limit the Secretary's prerogatives is clear. Senator Dominick explained his amendment as follows:

> What we were trying to do in the bill—unfortunately, we did not have the proper wording or the proper drafting—was to say that when we are dealing with toxic or physical agents, we ought to take such steps as are feasible and practical to provide an atmosphere within which a person's health or safety would not be affected. Leg. Hist. 502.

The plain import of the Javits and Dominick amendments is that the Secretary's efforts to protect employees must be tempered with an element of practicality and reasonableness. Given the concerns which Senators Javits and Dominick expressed, it is inconceivable that the amendments they offered contemplated that the Secretary would literally refuse to determine whether a major health standard would yield benefits. Obviously, Congress intended that the benefits of a standard would be of important concern to the Secretary. His decision to treat the matter as irrelevant here, evidenced by his refusal even to estimate benefits, was therefore irrational as a matter of law because he did consider all relevant factors. It also contravened the requirements of the Act, which as shown, command an evaluation of the reasonableness of a standard, and specifically direct the Secretary to consider the "best available evidence" and the "latest available scientific data in the field."

D. Decisions addressing the benefit issue: the noise cases

That the benefit to be derived from a standard is not only a relevant, but also a mandatory, consideration under the Act is confirmed by decisions of OSHRC and the courts construing OSHA's standard governing exposure to noise. In *Continental Can, supra,* OSHRC analyzed the Congressional intent relating to the economic "feasibility" of OSHA standards, and concluded:

> * * * the standard should be interpreted to require those engineering and administrative controls which are economically, as well as technically feasible even though they are expensive and increase production costs. See *Arkansas Best Freight Systems, Inc.* [v. *OSHRC,*] 529 F.2d 649, 653 (8th Cir. Jan. 29, 1976); *Industrial Union Department, AFL-CIO* v. *Hodgson, supra,* 449 F.2d at 477 [(D.C. Cir. 1973)]. But they will not be required without regard to the costs which must be incurred and the benefits they will achieve. In determining whether controls are economically feasible, *all the relevant cost and benefit factors must be weighed.*[23]

OSHRC has subsequently reaffirmed and applied this standard several times.[24]

Both the Sixth and Seventh Circuits have embraced OSHRC's view. Thus, in *Turner Co.* v. *Secretary of*

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[23] 4 BNA OSHC at 1547 (emphasis added).

[24] *Atlantic Steel Co.,* 6 BNA OSHC 1289, 1977-78 CCH OSHD ¶ 22,843 (1978); *Castle & Cook Foods,* 5 BNA OSHC 1345, 1977-78 CCH OSHD ¶ 21,854 (1977), petition for review pending (9th Cir. No. 77-2565-66); *Great Falls Tribune Co.,* 5 BNA OSHC 1443, 1977-78 CCH OSHD ¶ 21,844 (1977).

Labor,[25] OSHRC had taken a position contrary to the one it expressed in *Continental Can,* and had ordered the employer to install engineering controls designed to reduce noise levels at a cost of approximately $30,000. The employer had an effective program of personal protective equipment, and demonstrated that no employee had suffered hearing loss. The Seventh Circuit determined to adopt the analysis of the legislative history of the Act contained in OSHRC's *Continental Can* decision, and held that the Review Commission must "realistically consider the hazards presented by the excessive noise . . . and determine whether the health benefits . . . justify the $30,000 cost to Turner for engineering controls." [26]

The Sixth Circuit has set forth in detail its view of the role that consideration of benefits and relative costs plays in the application of OSHA standards. Thus, in *RMI Co.* v. *Secretary of Labor and OSAHRC,*[27] the Court stated:

> We approve the above-stated cost-benefit analysis employed by the OSHRC [in *Continental Can*].
>
> It must be emphasized that the primary purpose of the statute and regulations is 'to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve human resources.' 29 U.S.C. § 651(b). Thus the benefits to employees should weigh heavier on the scale than the costs to employers. Controls will not necessarily be economically infeasible merely because they are expensive.

[25] 561 F.2d 82 (7th Cir. 1977).

[26] 561 F.2d at 85-86.

[27] 594 F.2d 566 (6th Cir. 1979).

> But neither will controls necessarily be economically feasible merely because the employer can easily (or otherwise) afford them. In order to justify the expenditure, there must be a reasonable assurance that there will be an appreciable and corresponding improvement in working conditions. The determinations of how the cost-benefit balance tips in any given case must necessarily be made on an *ad hoc* basis. We do not today prescribe any rigid formula for conducting such analysis. We only insist that the Secretary, and the OSHRC on review weigh the costs of compliance against the benefits expected to be achieved thereby in order to determine whether the proposed remedy is economically feasible.[28]

Turner, RMI and the OSHRC decisions [29] make it clear that the benefits of a standard are an important factor which the Secretary must consider.[30]

[28] 594 F.2d at 572-73.

[29] See discussion and cases cited *supra,* p. 21.

[30] In *Turner,* the Sixth Circuit noted its agreement with the Review Commission's comment in *Castle & Cook, supra,* that other hazards may be more serious or "life threatening" than noise. 561 F.2d at 86. It appears that the Court offered this comment at least in part to justify its conclusion that the costs and benefits of engineering controls to abate noise should be balanced. However, the Court's comment cannot be construed to mean that similar considerations do not apply to standards governing more dangerous hazards. First, Section 6(b)(5) of the Act makes no such distinction; the factors which it commands the Secretary to consider apply to all standards governing "toxic materials or harmful physical agents." Indeed, this was exactly one of the points of the Dominick amendment to Section 6(b)(5). See discussion *supra,* p. 19. Second, it is precisely because all substances and physical hazards do not pose the same degree of risk that an estimation of the benefits to be derived from standards must be made. Otherwise, there would

E. The evidence that an analysis of benefits could have been performed.

The Secretary defends his action chiefly on the ground that any analysis of benefits would have required precise quantification of those benefits, and that such quantification is impossible because there is no known dose-response curve for benzene. However, as noted earlier, a broad range of analytical techniques could have been applied to develop at least a "rough but educated" estimate of the benefits of the standard which would have been useful to the Secretary.

It must be noted at the outset that there is no single form of cost-benefit analysis, cost-effectiveness analysis, risk assessment or of synonomous or similar techniques.[31] The available approaches "range from the narrow and technical to the broad, vague, almost metaphysical." [32] Thus, we do not, and could not, urge that

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be no rational way to allocate the finite resources available to deal with these various risks.

See also *Florida Peach Growers Ass'n* v. *Dep't of Labor, supra,* 489 F.2d at 130. ("The promulgation of any standard will depend upon a balance between the protection afforded by the requirement and the effect upon economic and market conditions in the industry."); *United Parcel Service of Ohio, Inc.* v. *OSHRC,* 570 F.2d 806, 810-13 (6th Cir. 1978) ("the rule to be applied is one of reasonableness and feasibility.").

[31] Kasper, *Cost-Benefit Analysis in Environmental Decisionmaking,* 45 Geo. Wash. L. Rev. 1013 (1977).

[32] *Id.* Accord: Green, *Cost-Risk-Benefit Assessment and the Law: Introduction and Perspective,* 45 Geo. Wash. L. Rev. 901, 902 (1977); R. Smith, *The Occupational Safety and Health Act, Its Goals and Achievements* 42 (American Enterprise Institute, 1976).

a particular analytical procedure be imposed upon the Secretary.[33] To the contrary, a number of analytical techniques could have been applied to yield an estimate of benefits. Moreover, a "rough but educated estimate"

At attempt has been made to reduce the "diffuse and difficult" literature on this subject into a form "lawyers could comprehend and use." Albert, *Some Epistemological Aspects of Cost-Benefit Analysis,* 45 Geo. Wash. L. Rev. 1025, 1026 (1977). Having bravely undertaken this effort, Professor Albert concluded with relevance to the instant case:

> [W]e face an urgent need for precise rules to measure the adequacy of information on which administrative cost-benefit decisions are to be made. This quest, though perhaps uncongenial to the legal mind, is the key to answering the fundamental question: What decision do sane people make while waiting for the facts to be determined? *Id.* at 1035-36 (footnotes omitted).

[33] It is not our view that the "statutory minima" require use of a particular procedure. Compare, *Vermont Yankee Nuclear Power Corp.* v. *Natural Resources Defense Council, Inc.,* 435 U.S. 519, 548 (1978). Rather, we urge only that the statute requires consideration of the benefits to be derived from the standard.

In a recent article, Judge Bazelon has wondered whether *Vermont Yankee* "will herald a new era of good feelings or instead exacerbate the tension created by judicial review . . ." Bazelon, *Risk Regulation and Responsibility,* 65 Am. Bar Ass'n J. 1066, 1069 (1979). Judge Bazelon indicated his general endorsement of Professor William Rodgers' analysis of *Vermont Yankee. Id.* With substantial relevance here, Professor Rodgers has suggested that *Vermont Yankee* should not be read as "discouraging remands to correct record weaknesses that are best improved by resort to specific procedural techniques," or "to take the impetus out of the agencies' innovative use of procedures beyond the statutory minima." Also, agencies should not be permitted to invoke the decision to defend "crabbed rationalizations of adopted rules." Rodgers, *A Hard Look at Vermont Yankee: Environmental Law Under Close Scrutiny,* 67 Geo. L. J. 699, 714-15 (1979).

of benefits is exactly what the Court below requested;[34] indeed, the Court expressly disclaimed any intention of requiring an elaborate cost-benefit analysis.

The Secretary's view that even such a "rough" analysis could not be performed is contradicted by the record evidence of the recommendations of the Council on Wage and Price Stability ("COWPS") and the Department of Health, Education and Welfare ("HEW") concerning the proposed standard. COWPS concluded that the proposal did "not reflect sufficient considerations of the costs and attendant health benefits of the standard," and that such an analysis was "critical."[35] COWPS outlined in detail the analytical procedures it believed the Secretary should employ. COWPS also recognized, as we have emphasized here, that while the analyses it suggested might not yield "an accurate calculation of incremental benefits, they would provide a range of health benefit estimates that should be included in an economic analysis in order to aid OSHA in setting the final standard."[36] HEW's comment was somewhat more direct, admonishing OSHA that "real world pragmatism requires a systematic decisionmaking process" that takes cognizance of the varying degrees of potencies among carcinogens.[37]

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[34] 581 F.2d at 504.

[35] Appendix at 121, 131.

[36] Appendix at 130.

[37] Letter of Charles Custard, Director of HEW Office of Environmental Affairs, dated July 12, 1977 (Ex. 205.A).

The significant point about the COWPS and HEW recommendations is not that two government agencies disagree with the Secretary on an issue which transcends OSHA and touches all risk-

A "rough but educated" estimate of benefits—not precise incremental analysis—is what others besides COWPS and HEW recommended during the proceedings before the Secretary. For example, Dr. Richard Zeckhauser of the Kennedy School of Government at Harvard University testified:

> While I appreciate the fact that the limited data available make it impossible, as the [Arthur D. Little] study suggests . . . to specify 'benzene's precise dose-response relationship,' it is also impossible to evaluate the standard in any meaningful way without some estimate, *however crude,* of its benefits. Even if such an estimate could not be refined beyond a broad range of possible effects, it would be of immense value. From the documents I have seen, we have no idea whether the proposed standard would save no lives, ten lives, or 1000 lives for an annual expenditure of more than $100 million. At the very least OSHA should present a range of estimates of the health losses due to current levels of exposure to benzene. With such estimates it would be possible to place an upper bound on the incremental gains of the proposed standard, as OSHA admits that it will not eliminate all health effects.[38]

Besides aiding the Secretary in determining the appropriate exposure level, an analysis of benefits, "however crude", would have helped him evaluate other portions of the standard as well. For example, the

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regulating agencies, although that fact is surely a disturbing one. The point is that record support for the Secretary's decision not to perform an analysis of the benefits of the standard is substantially weakened by the evidence of the views of COWPS and HEW.

[38] Appendix at 144 (emphasis added).

analysis could have helped determine how many medical examinations of workers exposed to benzene are needed annually, or what changes in information gathering might occur if the expenditures for monitoring programs are reduced or raised by a certain percentage from the expenditure amount contemplated in the proposed standard.[39]

As the Court below noted, the Secretary did not instruct Arthur D. Little Company, his consultant on the feasibility of the standard, to examine the benefits of the standard. The consultant testified, however, that some analysis of risk quantification could have been performed had it been requested. The Court also noted that the Environmental Protection Agency had recently released a Preliminary Report on Population Risk to Ambient Benzene Exposures, which attempted to determine the risk of leukemia to the general population at the exposure level of 1 ppm.[40]

In sum, the record contains ample proof that at least a "preliminary assessment" of the risks associated with benzene are being made, and that analytical techniques which would have enlightened the Secretary on this issue could have been utilized, but were not.

F. Summary

We have shown that the plain language of the Act, its legislative history, and the authorities which have construed them in connection with the instant question combine to leave no doubt that the Secretary was obligated to consider the benefits of the standard under

[39] *Id.* at 141.

[40] 581 F.2d at 504 n.23.

review. We have also shown that the record supports the conclusion that a useful estimate could have been performed, and that his decision not to perform the estimate is unsupported by substantial evidence. It is likewise clear that the Secretary failed to consider all of the factors relevant to this decision, and thus acted arbitrarily and capriciously in the traditional administrative law sense. He also ignored the requirements of the Act, most pertinently Section 6(b)(5), which commands that he regulate on the basis of the "best available evidence" and "the latest available scientific data in the field." Finally, inasmuch as his declaration that the benefits of the standard may be "appreciable" is bottomed on nothing more than an "assumption," his factual finding on this key point is unsupported by substantial evidence. Accordingly, the standard is invalid, and the judgment of the Court below should be affirmed.

III. Important Public Policy Objectives Would Be Served by Requiring an Analysis of the Benefits of OSHA Standards

In his recent discussion of risk regulation, Judge Bazelon has commented that "there is no one answer" to the question of "how much risk is acceptable." Judge Bazelon thus concludes that "we must have confidence in the decision-making process so that we may better tolerate the uncertainties of our decisions."[41] As we have emphasized here, more specific procedural safeguards are not the answer.

> It is not the procedures but the fullness of the inquiry that is paramount. If the inquiry is comprehensive and conscientious without additional procedural safeguards, it provides the best record we

[41] Bazelon, *supra* note 33, at 1066-67.

can hope for in making the difficult choices we now face.[42]

Here, the Secretary's inquiry was hardly a full one. By refusing to analyze benefits, he not only gave short shrift to an important statutory consideration, but he also went far to undermine the public's confidence in his decision. This Court's condonation of his actions could only be interpreted by the Secretary and by other comparable federal administrators as a license to conduct less than the fullest exploration of the complex matters that confront them. As Judge Bazelon has suggested, judicial insistence upon full and complete administrative inquiry can only strengthen the administrative process upon which our society must rely in dealing with complex, technological issues of risk regulation. Thus, to approve the Secretary's decision here would be to countenance laxity in administrative analysis, a result which would ill-serve the public interest.

Perhaps the most important role the courts can perform in reviewing administrative actions such as the instant one is to assure that the value judgments implicit in such decisions are openly stated and acknowledged by the decision-maker. "If the decision-making process is open and candid, it will inspire more confidence in those who are affected." [43] As one commentator has stated:

> If governmental decisions are made openly those who remain subject to inequitable risks [or costs] are more likely to understand and accept the predominance of societal interest over their own. If such a process produces regulatory decisions ac-

[42] *Id.* at 1069.

[43] *Id.*

> ceptable to a substantial majority of our society, it will fulfill successfully the expectations of democracy.[44]

On the subject of value judgments, the Secretary and his supporters emotionally argue that any consideration of costs and benefits would necessarily involve the assertedly immoral act of "placing an economic value (implicit or explicit) on life, health, bereavement, pain and suffering, and other consequences of occupational disease and death." [45] The Foundation believes that this view reflects a distinctly immature approach to regulation. Administrators charged with implementing risk-regulation statutes are inevitably involved in placing monetary values on the human condition. Dr. Philip Handler, President of the National Academy of Sciences, has articulated this point particularly well:

> In the field of public health, implementation of regulations results in the expenditure of n dollars to spare m lives or prevent x cases of diarrhea or y cases of benign skin tumors or z cases of mercury-induced nephritis. And decision-making implicity, if not explicitly, entails picking out the value, for example, of saving a random life or of preventing a bout of diarrhea or skin tumor.

* * *

[44] Rowe, *Governmental Regulations of Societal Risks,* 45 Geo. Wash. L. Rev. 944, 958 (1977).

[45] Brief for the Federal Parties at 62 n.52. Of course, much of modern tort litigation is devoted to evaluating such consequences of injury, and statutory workman's compensation schedules reflect legislative evaluations of occupational injuries. Thus, the exercise which the Secretary eschews here is routinely performed by legislatures, administrative agencies, juries and courts.

> Since achieving zero risk is essentially impossible, decision will turn on the value, in dollars, which is placed on the marginal life. If those who engage in making such judgments—whether the costs are to be borne by the public purse or to be paid for by the consumer purchasing a product—do not understand that is what they are doing, *they are inadequately equipped for the task.*[46]

Contrary to the implication of the Secretary's brief, such considerations are hardly immoral. Indeed, to disclaim the obligation to place an economic value on the benefits of a risk regulation is intellectually dishonest:

> Even if it is considered morally objectionable to quantify the benefits of a safety or health program in explicit terms, one cannot escape the fact that any decision about such a program implies a set of benefits. It is more honest and useful to quantify these benefits explicitly than it is to pretend that one is 'above' such a 'dollars-and-cents' approach and then value the benefits implicitly.[47]

In sum, in response to the argument that regulators should not place an economic value on benefits, Dr. Handler states:

> Nonsense. Value judgments are dollar considerations.[48]

Even assuming that the Secretary is reticent about expressing his value judgments in monetary terms, that is no excuse for not estimating the benefits of an OSHA

[46] Handler, *A Rebuttal: The Need for a Sufficient Scientific Base for Government Regulation*, 43 Geo. Wash. L. Rev. 808, 810, 811 (1975) (emphasis added).

[47] Smith, *supra* note 28 at 36-37.

[48] Handler, *supra* note 46 at 810.

standard. As the Fifth Circuit has stated with respect to the examination of alternative actions required under the National Environmental Policy Act of 1969 ("NEPA"):[49]

> Specific assignment of dollar values to environmental factors, which are frequently not amenable to quantification may not be necessary, if the impact statement otherwise recognizes, and discusses, and weighs the favorable and adverse effects of agency action.[50]

Another important reason why an analysis of the benefits of the standard should be required is to counterbalance the inevitable bias which the Secretary will feel in favor of his own proposals. Both courts and commentators have observed this phenomenon, noting that administrators "with a commendable zeal to accomplish their appointed goals, develop a mission orientation that prevents them from giving full cognizance" to opposing views.[51] It is precisely because Congress recognized that federal administrators can easily become infected by such biases that agencies subject to NEPA are required to prepare environmental impact statements under Section 102 of that statute. The statements must contain analyses of the advantages and disadvantages of proposed actions:

> NEPA assumes as inevitable an institutional bias within an agency proposing a project and erects the procedural requirements of § 102 to insure that there is no way [the administrator] can fail to note the facts and understand the very serious ar-

[49] 42 U.S.C. § 4321 et seq.

[50] *Robinson* v. *Knebel*, 550 F.2d 422, 426 (5th Cir. 1977).

[51] Note, *Cost-Benefit Analysis in the Courts: Judicial Review under NEPA*, 9 Ga. L. Rev. 417, 447, 428, n.81 (1977).

guments advanced by the [opponents of his action] if he carefully reviews the environmental impact statements.[52]

As stated earlier, we do not here advocate that a new procedure be engrafted upon the Secretary's rulemaking procedures that would rise to the level of formality of an environmental impact statement (although we note that the Third Circuit has held that OSHA is subject to Section 102 of NEPA.)[53] Our point is that the rationale for requiring such analyses under NEPA is equally applicable here, for the Secretary is no less susceptible to an institutional bias in favor of his proposals than any other federal administrator.

Finally, another purpose for preparing environmental impact statements under NEPA is applicable here. One purpose of NEPA is to "force agencies to *acquire* expertise" in evaluating the risks of proposed environmental regulations.[54] The record indicates that OSHA is notably lacking in such expertise. As Dr. Zeckhauser of Harvard testified, "OSHA has made little effort in the policy analysis area," and "should establish as a top priority the development of a policy

[52] *Environmental Defense Fund* v. *Corps of Engineers, U.S. Army*, 470 F.2d 289, 295 (8th Cir. 1972), cert. denied, 412 U.S. 931 (1973), quoted in *Sierra Club* v. *Froehlke*, 486 F.2d 946, 950 (5th Cir. 1973). Accord: *Silva* v. *Lynn*, 482 F.2d 1282 (1st Cir. 1973).

[53] *Dry Color Manufacturers Ass'n* v. *Dep't of Labor*, 486 F.2d 98 (3d Cir. 1973)). The Secretary has promulgated regulations implementing NEPA in his administration of the Act. 29 C.F.R. Part 1999 (1978).

[54] *Aberdeen and Rockfish Railroad Co.* v. *S.C.R.A.P.*, 422 U.S. 289, 331 (1975) (Douglas, J., dissenting) (Emphasis in original).

analysis capability . . ." [55] Dr. Zeckhauser noted that even if Arthur D. Little Company had performed an assessment of risks, the Secretary could have made little use of it or of other similar analytical tools "absent a strong policy analysis staff." [56] Thus, a decision compelling full analysis of risk issues in promulgating safety and health standards could have the salutary effect of improving the quality of the Secretary's analytical capabilities.[57]

IV. Costs and Benefits Should Be Quantified to the Extent Reasonably Possible in Promulgating OSHA Standards.

We noted earlier that while a precise, incremental analysis of the benefits of the instant standard may not have been possible, broad, preliminary estimates of such benefits were available to the Secretary. However, with respect to future OSHA standards, the precise information lacking here may be attainable. Accordingly, we would urge the Court not to hold that quantification of costs and benefits is necessarily inappropriate in the development of OSHA standards. We submit that where these factors are reasonably susceptible of being quantified in economic terms, that should be done. Where a particular factor is not reasonably susceptible of being quantified in economic terms

[55] Appendix at 140, 141.

[56] *Id.* at 145.

[57] Ordinarily, courts will defer to the expertise of an agency's technical staff on matters of scientific experience and knowledge. *United States ex. rel. Chapman* v. *FPC*, 191 F.2d 796, 808 (D.C. Cir. 1951), aff'd 345 U.S. 153 (1953), quoted approvingly in *FPC* v. *Florida Power & Light Co.*, 404 U.S. 453, 466 (1972). However, where, as here, the agency's technical staff does not possess that expertise, deference would be inappropriate.

but is reasonably susceptible of being quantified in terms other than economic, that should be done. Finally, where a factor is not susceptible of quantification in any terms, economic or otherwise, the Secretary should at least identify that factor in the statement of reasons supporting his decision in a manner sufficient to permit him to consider it with the other factors which are susceptible of quantification.

A Committee of the National Academy of Sciences has studied the use of risk assessment techniques in government decision-making and found that contrary to some expectations, the analyses were not used to rationalize pre-determined political decisions. Rather, the committee found that:

> explicit, quantitative analyses has not induced mere lip service, as some skeptics originally suggested. Rather, it has lead to increasingly careful and thoughtful evaluations that have improved appraisals of programs as well as the quality of project designs.[58]

As the National Academy of Sciences report suggests, there is substantial concern in the nation's scientific community that where, as is the case with major OSHA health and safety standards, there is going to be "a significant dislocation of society or the expenditure of large sums, such actions cannot rest on unquantifiable values alone."[59] As Dr. Handler has said, when the government proposes regulations to reduce the risk associated with technology, "an *attempt* is required to

[58] Committee on Environmental Decision Making, National Academy of Sciences, Decision Making in the Environmental Protection Agency 36 (1977) (hereinafter cited as "Committee, National Academy of Sciences").

[59] Handler, *supra* note 46, at 807.

state both the cost and the benefits in quantitative form."[60]

Scientists like Dr. Handler well recognize that "knowledge of risks is rather imperfect and knowledge of benefits is likely to be decidedly less satisfactory and stated in quite different terms."[61] Nevertheless, as he contends, the effort to quantify risks and benefits in some terms must be made. "Providing adequate quantitative bases for public decision-making," Dr. Handler, agrees, "is a function of the appropriate segment of the scientific community."[62]

Recognizing again that precise quantification of benefits may not have been possible in the instant case, it is apparent nevertheless that the Secretary did not reach out to the scientific community in an attempt to obtain "the best available" estimate of benefits or the "the latest available scientific data in the field". To the contrary, as shown above, the Secretary instructed his own consultant not even to attempt such an estimate.

In sum, while it may not be attainable in every case, the principle that "[g]overnment regulation of technical products or processes must rest on a rational and sufficient scientific base"[63] should be established as a regulatory goal. As Dr. Handler has stated:

> If such numbers are not known, if one deals only with perceptions, values, judgments, and safety,

[60] *Id.* (emphasis added). In addition to Dr. Handler's personal views, the Committee discussed above recommended the use of more systematic and explicit analysis of environmental regulation decisions. Committee, National Academy of Sciences, *supra*, note 58, at 9-10.

[61] Handler, *supra* note 46, at 807.

[62] *Id.* at 811.

[63] *Id.* at 813.

> the . . . public interest cannot intelligently be served.[64]

The Secretary can hardly oppose the establishment of this regulatory objective, for he has previously endorsed the notion that "systematic" cost-benefit analysis is desirable in formulating OSHA standards. For example, in announcing a standard governing exposure to acrylonitrile, the Secretary first disclaimed a statutory obligation to estimate the benefits of the standard, but then conceded:

> This does not mean, however, that a systematic evaluation of costs and benefits is not to be encouraged within the limits of the estimation techniques.[65]

More directly, the Secretary has asserted to Congress that his standard governing exposure to cotton dust reflects his choice of the most cost-effective alternative.[66] In sum, the Secretary has previously conceded that the use of benefit analysis is compatible with the statute, that it is not beyond his capability, and that it will *not* delay the Secretary from protecting workers. To the contrary, he has asserted that such analysis has aided him in arriving at a proper, rational standard.

The Secretary's contradictory statements on the desirability of analyzing costs and benefits in promul-

[64] *Id.* at 811.

[65] 43 Fed. Reg. 457 (Oct. 3, 1978); BNA Occ. Safety and Health Reporter 612 (Oct. 5, 1978).

[66] United States Dep't of Labor, "Report to Congress—Cotton Dust: Review of Alternative Technical Standards and Control Technologies," 14, 65, 67, 82 (May 14, 1979).

gating OSHA standards have an additional, important consequence in this case. In determining the weight which it will give to an administrator's interpretations of the enabling statute under which he operates, this Court has said that:

> [t]he weight of such a judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it the power to persuade, if lacking power to control.[67]

Here, the Secretary seeks the Court's deference to his judgment that the statute does not require an analysis of benefits, and that such analysis cannot be performed where carcinogens are involved. However, as shown, the Secretary's determination does not reflect a thorough analysis of the available scientific data and analytical techniques. To the contrary, it ignored them. Second, the Secretary's position here is inconsistent with positions he has espoused elsewhere. Third, his reasoning that the absence of a dose-response curve for benzene makes an analysis of benefits impossible and compels the lowest feasible level of exposure is invalid. As one commentator involved in risk regulation has stated:

> A determination of the 'as-low-as-practicable' limit on risk reduction is as arbitrary as a determination of the level of risk acceptance. Some other more stable reference is required to determine when risk reduction is cost-effective or when risk reaches an acceptable level.[68]

[67] *Skidmore* v. *Swift & Co.*, 323 U.S. 134, 140 (1944).

[68] Kasper, *supra* note 31, at 962. Dr. Kasper is Deputy Assistant Administrator for Radiation Programs, United States Environmental Protection Agency.

In sum, the Secretary's interpretation of the Act here does not satisfy the requirements of *Skidmore*. Accordingly, the Court should decline to follow that interpretation.[69]

V. Conclusion

We have demonstrated that careful evaluation of the benefits to be derived from a safety or health standard is mandatory under the Act. Therefore, by failing to estimate the benefits of the standard, the Secretary did not evaluate all of the factors relevant to the decision before him, and his action was thus irrational and unreasonable under settled principles of administrative law. Also, his determination that such an analysis was impossible is unsupported by substantial evidence. His omission also violated the commands of OSHA, particularly those of Section 6(b)(5), which require, *inter alia,* that standards be based on the "best available evidence" and the "latest available scientific data in the field." Further, the Secretary's failure to provide the estimate of benefits means that his finding that the benefits of the standard "may be appreciable" is unsupported by substantial evidence.

We have further demonstrated that for this Court to condone the Secretary's failure to explore fully the issues before him would be to encourage comparable federal administrators to act similarly, thus weakening the administrative processes upon which society must rely to resolve complex technological issues. This would be a development which the nation could ill-afford.

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[69] *Skidmore* v. *Swift & Co., supra:* Accord: *General Electric Co.* v. *Gilbert,* 429 U.S. 125, 141-43 (1976).

In sum, the actions of the Secretary in promulgating the instant standard governing exposure to benzene satisfy neither the law nor the public interest. For these reasons, we respectfully urge that the judgment of the Court below be affirmed.

Respectfully submitted,

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1978

No. 78-911

INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
Petitioner

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*

No. 78-1036

RAY MARSHALL, SECRETARY OF LABOR,
Petitioner

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF OF THE ANACONDA COMPANY AS AMICUS CURIAE

ALFRED V. J. PRATHER

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1978

No. 78-911

INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
Petitioner

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*

No. 78-1036

RAY MARSHALL, SECRETARY OF LABOR,
Petitioner

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF OF THE ANACONDA COMPANY AS AMICUS CURIAE

The Anaconda Company respectfully tenders this brief as *amicus curiae* for consideration of the Court. Anaconda supports the position presented by the American Petroleum Institute and urges the Court to uphold the decision of the United States Court of Appeals for the Fifth Circuit in this case.

THE INTEREST OF THE ANACONDA COMPANY

The OSHA cancer policy at issue in this case has been applied to The Anaconda Company and other copper producers who are challenging this policy in the United States Court of Appeals for the Ninth Circuit, which has deferred action pending decision of this case.[1] Thus the Court's decision here will directly affect the copper industry. Indeed, the effect on the copper industry may be greater than that involved for some of the industrial parties to this case because application of OSHA's cancer policy to the copper industry raises questions of feasibility more severe than the Solicitor admits here.[2]

OSHA's policy of setting the lowest standard thought feasible for carcinogens has been reviewed in several circuits with widely varying results. The pertinent statutory provisions are subject to conflicting interpretations as to what must go into OSHA's decision when it sets a standard and how much of that decision is reviewable by a court. The Solicitor's Brief is narrowly drawn to deal solely with the decision below, but the split between the circuits is much wider than such limited treatment reveals, and deserves further analysis in reaching resolution of this case. This brief is devoted to such analysis.

[1] *The Anaconda Company, et al.* v. *OSHA*, No. 78-2764, and *ASARCO Inc., et al.* v. *OSHA*, No. 78-1959. These cases challenge OSHA's arsenic standard, 29 C.F.R. 1910, 43 Fed. Reg. 19584 *et seq.*

[2] The Brief for the Federal Parties (hereinafter cited as "Solicitor's Brief") at pages 57-58 n. 50, asserts that economic feasibility is not in issue in this case, though it is a principal issue in the arsenic case. However, economic feasibility is a question of degree, and is necessarily involved to some degree in assessment of the OSHA cancer policy.

I. The Split In The Circuits Is Wider Than The Solicitor Suggests.

The Solicitor urges in his brief that the circuits are split as to whether the Secretary must explicitly balance costs against benefits when promulgating toxic materials standards. Solicitor's Brief at 42 & n.35. The Solicitor argues that the Fifth Circuit has required such balancing in the present case.[3] In contrast, the Second, Third, and D.C. Circuits require no further consideration of benefits once it has been shown that there may be no safe level of exposure to a proven carcinogen, focusing thereafter entirely upon the feasibility of the particular standard. See *American Iron & Steel Institute* v. *OSHA*, 577 F.2d 825, 831 (3d Cir. 1978), petitions for cert. pending, Nos. 78-918 and 78-919; *Society of Plastics Industry, Inc.* v. *OSHA*, 509 F.2d 1301, 1308-09 (2d Cir.), *cert. denied*, 421 U.S. 992 (1975); *Industrial Union Department, AFL-CIO* v. *Hodgson*, 499 F.2d 467, 475, 477-78 (D.C. Cir. 1974).

However, most circuits that have considered OSHA standards have required a cost-benefit balance in some situations. The courts have found two statutory pegs upon which to hang the requirement in those

[3] *American Petroleum Institute* v. *OSHA*, 581 F.2d 493, 503 (1978). The Solicitor may read too much into this opinion as to cost-benefit. The opinion seems more concerned with the Secretary's failure to weigh medical evidence properly. However, this brief will treat the Solicitor's argument as made, leaving to the parties discussion of whether the Solicitor has over-emphasized the cost-benefit language in the opinion below.

cases: (1) a reasonable necessity requirement; or (2) a feasibility requirement. The Eighth Circuit's rule is based upon both reasonable necessity and feasibility. See *United Parcel Service of Ohio, Inc.* v. *OSHRC*, 570 F.2d 806, 811-12 (1978). The Third and Fifth Circuits focus upon reasonable necessity. For example, the Third Circuit held that the Secretary may properly weigh the economic consequences of a national consensus standard against its effectiveness in deciding whether a change in the standard is necessary to better effectuate the purposes of the Act. 530 F.2d at 123. In a later discussion of that case, the court affirmed that "[T]he Secretary's rulemaking task comprehends weighing the competing considerations of economic burden and improvement of safety." *Atlantic & Gulf Stevedores* v. *OSHRC*, 534 F.2d 541, 548 (3d Cir. 1976). The Fifth Circuit has held likewise. See *Florida Peach Growers Association* v. *Department of Labor*, 489 F.2d 120, 129-30 (5th Cir. 1974).[4] In contrast, the Sixth and Seventh Circuits require cost-benefit balancing whenever feasibility must be considered. This requirement was clearly stated in *Turner Co.* v. *Secretary of Labor*, 561 F.2d 82 (7th Cir. 1977):

> ". . . we hold that the word 'feasible' . . . must be given its ordinary and common sense meaning of

[4] The Second Circuit might possibly be added to this list. In *Associated Industries of New York State, Inc.* v. *Department of Labor*, 487 F.2d 342 (2d Cir. 1973), the court, in ruling on the necessity of a national consensus standard, held that "when the Department imposes a standard considerably more stringent than that which has apparently been found satisfactory by many states with a long history of protection to industrial workers . . . then it has an obligation to produce some evidence justifying its action." 487 F.2d at 352-53.

> 'practicable.' This construction is in accord with the clear intent of Congress and the purpose of the Occupational Safety and Health Act. Accordingly, the Commission erred when it failed to consider the relative cost of implementing engineering controls . . . versus the effectiveness of an existing personal protective equipment program . . . ." 561 F.2d at 83-84.

Accord. *RMI Co.* v. *Secretary of Labor*, 594 F.2d 566, 571-72 (6th Cir. 1979).

These cases in which the circuits have required a cost-benefit analysis hold the key to the split on permanent toxic materials standards. The Fifth Circuit, in the present case, has extended the reasonable necessity rationale to require balancing in that context. 581 F.2d at 503. While the Sixth and Seventh Circuits have as yet considered no permanent toxic materials standards, the feasibility basis of the cost-benefit balance they have required in other OSHA cases mandates extension of the requirement to cases involving permanent toxic materials standards.[5] Conversely, although the Second, Third and D.C. Circuits have implicitly rejected a cost-benefit balancing requirement

[5] A close look at the decisions of these circuits confirms this view. Though the Seventh Circuit in *Turner Co.* was construing "feasible" as used in the standard under review and not the Act itself, it clearly considered its construction to be "in accord with the clear intent of Congress and the purpose of the Occupational Safety and Health Act." 561 F.2d at 83, 85. The Sixth Circuit in *RMI Co.* tied its feasibility definition directly to the feasibility requirement of section 6(b)(5). 594 F.2d at 571. Neither of these decisions comes close to holding, as the Solicitor suggests, that a "ban on 'life-threatening hazards' such as industrial carcinogens would not be subject to any cost-benefit test . . . ." See Solicitor's Brief at 42 n.35.

based upon feasibility, they have not considered the reasonable necessity rationale.[6]

Thus, the Solicitor's suggestion that the only disagreement on the cost-benefit balancing issue is between the Fifth Circuit and all other circuits ignores at least two basic disagreements lurking beneath the surface of this issue: the potential split between the Fifth Circuit and the Third Circuit as to the extension of the reasonable necessity rationale to cases involving permanent toxic materials standards, and, more importantly, the split between the circuits that construe the Act's feasibility requirement as mandating a cost-benefit balance and those that construe it to

[6] The Fifth Circuit expressly mentioned this fact in its opinion below. 581 F.2d at 505. There is some reason to believe that the Third Circuit might prove receptive to the reasonable necessity rationale. As previously mentioned, it has accepted the rationale in the context of other types of OSHA standards. See page 4, *supra*. Moreover, in *Dry Color Manufacturers' Association, Inc.* v. *Department of Labor*, 486 F.2d 98, 107 (3d Cir. 197e), the court vacated an emergency temporary toxic materials standard because the Secretary had failed to explain why the particular standard chosen was necessary to protect employees. Conversely, in *Synthetic Organic Chemical Manufacturers Association* v. *Brennan*, 503 F.2d 1155 (3d Cir. 1974), *cert. denied*, 420 U.S. 973 (1975) ("SOCMA I"), the Court failed to discuss petitioner's contention that the particular standard chosen by the Secretary was unnecessary to protect workers. 503 F.2d at 1157. That case, however, involved a permanent toxic materials standard and petitioners failed to direct the court's attention to any statutory requirement of reasonable necessity. *Id.* The court has elsewhere noted that the Secretary "has an affirmative burden to demonstrate the reasonableness" of all standards subject to judicial review under the Act. *Atlantic & Gulf Stevedores* v. *OSHRC*, 534 F.2d 541, 551 (3d Cir. 1976).

In view of its decision in *Associated Industries*, the Second Circuit might likewise prove receptive to the reasonable necessity rationale. See note 4, *supra*, page 4.

require consideration of costs only, making the meaning of the Act's feasibility requirement an important issue in this case.

II. The Secretary's Feasibility Determinations Should Be Expressly Subjected To The Act's Substantial Evidence Requirement.

Anaconda believes that the briefs of the parties will adequately explore the issue whether the reasonable necessity or feasibility mandates of the Act require the Secretary to balance the costs of a standard against its benefits. However, if the Court were to construe "feasible" as requiring consideration of costs only and uphold the Secretary's "lowest feasible level policy," as the Solicitor urges, the propriety of the Secretary's determination of costs would become tbe central issue in nearly all toxic materials cases.[7] Thus, it is important that the Court, in passing upon these issues, be aware of the ways in which this determination has been made.

A. *The Secretary Has Not Always Applied The Solicitor's Concept of Feasibility.*

The Secretary has applied a concept of feasibility far more stringent than that described in the Solicitor's brief. According to the Solicitor, cost considerations "necessarily play a substantial role in the Secretary's determination that a particular level of ex-

[7] The Solicitor confirms that the policy has been applied in almost all toxic materials cases because the Secretary has been unable to determine a safe level of exposure for such substances. Solicitor's Brief at 72-73.

posure is feasible." Solicitor's Brief at 57 n.50. "Feasible" is variously defined as "practicable," "achievable at bearable cost with available technology," and "capable of being achieved at acceptable cost." *Id.* at 55, 57, 58. A policy embracing these concepts of feasibility is alleged to have been applied in all eight toxic materials cases, with a citation to a footnote in which seven of the eight are listed as proof of consistent application. *Id.* at 72, 21 & n.24. The arsenic case is conspicuously absent from this list, as well it might be, for the concept of feasibility applied in that case bears little resemblance to any of the above descriptions.

The arsenic case offers a prime example of the way in which such vague phrases as "bearable cost," "acceptable cost," and "available technology" can be so convoluted as to render the feasibility determination upon which the Solicitor places so much dependence entirely meaningless. The arsenic standard is purportedly based solely upon feasibility. 43 Fed. Reg. 19600-01 (May 5, 1978). However, feasibility is defined as "the lowest level achievable through engineering controls and work practices in the majority of locations." 43 Fed. Reg. 19601. Further text explains that Anaconda and other copper companies processing ore containing significant amounts of arsenic will not be able to achieve compliance by use of engineering controls and work practices. 43 Fed. Reg. 19601-04. These companies, which account for approximately half of the industry's annual tonnage of concentrates, are to install all feasible equipment, adopt all feasible protective work processes, and compensate for their inability to meet the standard by requiring workers to wear respirators. *Id.* Respirators, however,

are considered undesirable and are to be used only on a temporary basis: the companies will ultimately be required to meet the standard. *Id.* Progress toward this end is to be supervised by OSHA on a case-by-case basis under the Act's enforcement provisions, which prescribe civil and criminal penalties. In short, the Secretary has established a standard which he admits is technologically infeasible for smelters with significant amounts of arsenic in their feed—the only ones for which "feasibility" is really an issue—and is subjecting the companies to an enforcement program placing them at the mercy of subjective future decisions of feasibility.

This approach to feasibility bears no resemblance to the concept as described in the Solicitor's brief. How can the costs of reaching a given exposure level be "bearable" or "acceptable" when the required technology is not even "available"? If the technology needed to comply with a standard is unknown, certainly its costs cannot be known. As a result, Anaconda and fully half of the copper industry are subjected to an open-ended obligation to spend whatever the Secretary may require in the future in an effort to meet an infeasible standard. This presents these companies with immediate practical problems because the risk of incurring such unknown costs in the future must be accounted in deciding whether to make additional expenditures today. Few companies can afford the luxury of making substantial investments today subject to an undefined obligation to spend additionally whatever the Secretary may require tomorrow in pursuit of compliance with an infeasible standard. Certainly Anaconda can afford no such luxury. Just as certainly, this approach cannot be

squared with the concept of feasibility as defined by the Solicitor.

B. *Congress Intended To Require Feasibility Decisions To Be Made On The Basis Of Substantial Evidence.*

Under the Act, determinations made by the Secretary are conclusive only if supported by "substantial evidence in the record considered as a whole." 29 U.S.C. §655(f)(1975). This provision is fully applicable to all standard-setting determinations, including the feasibility determination required by Section 6(b)(5). See, *e.g., Florida Peach Growers Association* v. *Department of Labor*, 489 F.2d 120, 126 (5th Cir. 1974); *Industrial Union Department, AFL-CIO* v. *Hodgson*, 499 F.2d 467, 472, n.11 (D.C. Cir. 1974). The precise meaning of the substantial evidence standard in the context of setting occupational safety and health standards, however, has been subject to some question in the courts of appeal. Given the impossibility of knowing what standard, if any, is truly needed to protect workers in some cases, it is understandable that some courts label decisions in this area "policy making" or "legislative" or "on the frontier of scientific knowledge" and exclude them from the substantial evidence test Congress has prescribed for review of OSHA standards.[8]

Regardless of the propriety of this approach to decisions involving health effects, it clearly cannot ap-

[8] See, *e.g., AFL-CIO* v. *Brennan*, 530 F.2d 109, 115-16 (3d Cir. 1975); *Society of Plastics Industry, Inc.* v. *OSHA*, 509 F.2d 1301, 1308 (2d Cir.), *cert. denied*, 421 U.S. 992 (1975); *Industrial Union Dep't, AFL-CIO* v. *Hodgson*, 499 F.2d 467 (D.C. Cir. 1974).

ply to feasibility decisions. In the first place, even the most "liberal" courts have strictly applied the substantial evidence standard to all "factual matters subject to evidentiary development." See, *e.g., IUD* v. *Hodgson*, 499 F.2d at 475-76; *Synthetic Organic Chemical Manufacturers Association* v. *Brennan*, 503 F.2d 1155, 1160 (3d Cir.), *cert. denied*, 420 U.S. 973 (1975) ("SOCMA I"). One could hardly imagine matters more clearly within this category than economic and technological feasibility.

More importantly, the legislative history of Section 655(f) (original Section 6(f)) clearly indicates that Congress intended the substantial evidence standard to be strictly applied to all of the Secretary's decisions in setting standards under the Act. The differing House and Senate versions of the legislation considered by the Conference Committee provided for different standards of judicial review. Section 6(f) of the Senate bill provided for pre-enforcement judicial review of standards but specified no standard for review; thus, presumably, the governing standard would have been the standard applicable to rulemaking under the Administrative Procedure Act. S. 2193, 91st Cong., 2d Sess. §6(f) (1970). As the bill did not require the Secretary to promulgate standards "on the record after opportunity for an agency hearing," the "arbitrary and capricious" standard would bave been applicable under Section 706(A)(2), 5 U.S.C. §706(A)(2). The committee report accompanying the Senate bill made no mention of the standard for pre-enforcement review. See S.Rep.No. 91-1282, 91st Cong., 2d Sess. (1970).

The House bill as reported out of committee originally contained no provision concerning pre-enforce-

ment judicial review of standards. See H.R. 16785, 91st Cong., 2d Sess. (1970). In subsequent debate on the floor of the House, Representative Steiger, in proposing a substitute bill (known as the Steiger-Sykes Amendment), noted of the committee version that "in standard-setting, there is no provision for judicial review." 116 Cong. Rec. H10680 (daily ed., Nov. 24, 1970). Thus, the proposed substitute bill, as finally adopted on the House floor, provided for pre-enforcement judicial review of standards and specified that "review by the court shall be in accordance with the provisions of Section 706 of Title 5 of the United States Code." H.R. 16785, 91st Cong., 2d Sess. §13(c) (1970); 116 Cong. Reg. H10697 (daily ed., Nov. 24, 1970). As Section 7(a)(3) of the bill required standards to be promulgated "upon the entire record" before the Secretary, the resulting standard of review would have been the "substantial evidence" standard under Section 706(2)(E). This conclusion is reinforced by the fact that an earlier version of the House bill had provided for substantial evidence review of the Secretary's findings of fact in the promulgation of standards. H.R. 17748, 90th Cong., 2d Sess. §3(d)(4) (1968); see H.R. Rep. No. 1720, 90th Cong., 2d Sess. 25 (1968). In any event, the Conference Committee adopted the previously quoted language of the Act which was finally passed by both houses.

At one point in time, the Government made much of an alleged ambiguity in the Conference Report, where the House managers state:

> "The 'substantial evidence' test was the basis of court review in the House amendment; in the Senate bill, the more vigorous standards generally applicable to review of rules would have been applicable. Review of the local court of appeals, the use of the 'substantial evidence' test, and a 60-day limitation on the appeal time were accepted by the conferees." H.R. Rep. No. 91-1765, Conference Report, 91st Cong., 2d Sess. 36 (1970).

In earlier litigation involving this passage, the Government contended that the conferees mistakenly assumed that "standards generally applicable to review of rules" (the arbitrary and capricious standard) were "more vigorous" and that the quote shows that the conferees intended to adopt what they considered the weaker standard for review. The courts to which this argument was presented refused to accept it. Speaking for the Second Circuit in *Associated Industries of New York State, Inc.* v. *Department of Labor*, 487 F.2d 342 (1973), Judge Friendly found that:

> "Whatever the explanation of the House managers' having said 'more vigorous' rather than 'less vigorous,' the intention to adopt the substantial evidence test for review as a tradeoff for the House's abandoning its insistence on rulemaking on the record, which would automatically have invoked that test under 5 U.S.C. §706(2)(E), is apparent." 487 F.2d at 349.

The Fifth Circuit, in *Florida Peach Growers Ass'n* v. *Dep't of Labor*, 489 F.2d 120 (1974), likewise explained:

> "The conferees accommodated the Senate's desire for administrative convenience and flexibility by accepting informal rulemaking procedures, but placated House concern for protection of employers from arbitrary burdens imposed by a massive federal bureaucracy, but [sic] adopting the substantial evidence test for judicial review. Thus . . . Congress applied that test as a result of a legislative tradeoff." 489 F.2d at 128.

Regardless of the interpretation of this ambiguity in the Conference Report, the statute does say "substantial evidence," and the excerpt from the Conference Report demonstrates that the inclusion of the substantial evidence standard was the result of a legislative tradeoff specifically designed to insure adequate protection of employers and thus was meant to apply to all standard-setting decisions of the Secretary.

An apparent error in the presentation of Section 6(f) as reported to the respective houses out of the Conference Committee may add some weight to the contention that the substantial evidence standard governs all types of decisions. The Conference Committee's final version of Section 6(f), as introduced in the House by Representative Perkins on December 16, 1970, was identical to the previously quoted provision now contained in 29 U.S.C. §655(f):

> "The *determinations* of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole." 116 Cong. Rec. H11803 (daily ed., Dec. 16, 1970) (emphasis supplied).

The final version of Section 6(f) as introduced on the same date in the Senate by Senator Williams of New Jersey, however, reads as follows:

> "The *findings of fact determinations* of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole." 116 Cong. Rec. S20272 (daily ed., Dec. 16, 1970) (emphasis supplied).

It seems incredible that the language of Section 6(f), ostensibly introduced as part of a common conference report, could vary in such a manner. No one

seems to have noticed the difference. It is not mentioned in either the conference report or the floor remarks preceding acceptance of the Conference Committee's bill. The origin of the language "findings of fact determinations" is anyone's guess. It could have come from the previously mentioned 1968 version of the House bill. See H.R. 17748, 90th Cong., 2d Sess. §3(d)(4) (1968). It could have originated with the conferees. At any rate, it is certain, from the text of the statute as it presently exists, that this language was ultimately rejected. This implies that the conferees specifically rejected the alternative of limiting the applicability of the substantial evidence standard to the Secretary's findings of fact, and supports the proposition that the substantial evidence standard, as contained in the Act, applies to all types of "determinations" made by the Secretary.

Finally, the argument can be made that the term "determinations of the Secretary" as used in the Act necessarily includes all determinations made in the promulgation of standards; thus only the substantial evidence standard can apply to these determinations. Section 6(b)(1) of the Act, 29 U.S.C. §655(b)(1), provides that the first step in the promulgation of a standard is that the Secretary "determines" that the standard should be promulgated. Likewise, Section 6(e), 29 U.S.C. §655(e), which requires the Secretary to state his reasons for promulgating a standard, is entitled "Statement of Reasons for Secretary's *Determinations*" (emphasis supplied). This argument was well received by the Second Circuit in *Associated Industries of New York State*, 487 F.2d at 348 & n.5. Moreover, there is one supportive piece of legislative history. In urging the House to accept the compro-

mise bill as reported out of the Conference Committee, Representative Steiger, a principal author of the bill, stated:

> "The permanent standards-setting machinery provides for a hearing upon request of an interested person following judicial review, as are other standards promulgated under Section 6, by an appropriate Federal court of appeals. The Secretary's *standard* will be sustained by the court only if it is supported by 'substantial evidence in the record considered as a whole.' " 116 Cong. Rec. H11899 (daily ed., Dec. 17, 1970) (emphasis supplied).

These materials clearly demonstrate that Congress intended the Secretary to produce substantial evidence in support of all determinations made in setting occupational safety and health standards. This requirement is especially applicable to feasibility determinations, which unquestionably concern "matters subject to evidentiary development." Under this approach, guesswork thinly disguised as a "policy determination" is unacceptable because Congress has already *made* the "legislative" decision as to what standards are feasible "on the frontiers of scientific knowledge." Congress has refused to allow the Secretary to venture into the unknown beyond the limits of substantial evidence demonstrating that his standards are feasible. Anything less is bound to produce infeasible standards in violation of the mandate of Section 6(b)(5), precisely the result in the arsenic case. If the Court upholds the "lowest feasible level" policy, it should protect against such a result by requiring the policy to be applied in conformance with the Act's substantial evidence requirement.

CONCLUSION

The split between the circuits on the basic issues raised by this case cannot be resolved without going beyond the narrow cost-benefit question central to the Solicitor's brief. Whatever the economic terminology—cost-benefit, feasibility or other—the question requiring resolution is the extent to which OSHA's cancer policy is subject to the standard-setting and judicial review provisions of the Occupational Safety and Health Act. The course urged by the Solicitor would confer such a high degree of discretion upon the Secretary as to invite arbitrary administrative action and preclude meaningful review. Enforcement of the substantial evidence standard prescribed by Congress would properly limit the scope of the Secretary's discretion in considering the costs and benefits of toxic materials standards.

Respectfully submitted,

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IN THE

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On Writ of Certiorari to The United States Court of Appeals For The Fifth Circuit

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BRIEF OF ASARCO INCORPORATED AS AMICUS CURIAE

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1978

No. 78-911

INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, ET AL.,
Respondents.

No. 78-1036

RAY MARSHALL, SECRETARY OF LABOR,
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, ET AL.,
Respondents.

On Writ of Certiorari to The United States Court of Appeals For The Fifth Circuit

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BRIEF OF ASARCO INCORPORATED AS AMICUS CURIAE

INTEREST OF THE AMICUS CURIAE

ASARCO is a leading smelter of non-ferrous metals. As such, it is directly affected by many occupational safety and health regulations promulgated by the Sec-

retary of Labor[1] under the statute here involved, the Occupational Safety and Health Act of 1970, 84 Stat. 1590, 29 U.S.C. §§ 651-678 (hereinafter "the Act"), and has a direct interest both in the substantive provisions of such regulations and in the standards and procedures governing their adoption. ASARCO is a party to two major proceedings for the review of OSHA regulations: No. 79-1048 and consolidated cases in the United States Court of Appeals for the District of Columbia Circuit, for review of OSHA's inorganic lead standard; and No. 78-1959 and consolidated cases in the United States Court of Appeals for the Ninth Circuit, for review of OSHA's inorganic arsenic standard. Those proceedings raise sundry issues not involved in the case at bar. ASARCO believes that the petitioners have stated the issues herein too broadly and that they seek to have the Court deal with questions not necessary to the decision and to prejudge questions better dealt with on the full records of other cases, including ASARCO's pending proceedings. ASARCO accordingly files this brief *amicus curiae* both in its own interest and in the hope that doing so will further "the public interest in the administration of justice." *Universal Oil Co.* v. *Root Refining Co.*, 328 U.S. 575, 581 (1946). Written consents from all parties to the filing of this brief are on file with the Clerk.

[1] We refer interchangeably herein to "the Secretary" and to "OSHA".

ARGUMENT

I. The Essential Element Of The Holding Below Is That There Is No Evidence That The Burdensome And Costly Regulation Here Involved Is Directed At A Real Hazard.

A. The facts.

The operative facts herein are few and simple.

Benzene can be toxic in sufficiently high concentrations. In high enough concentrations it can cause leukemia. Previous OSHA regulations impose a permissible exposure limit ("PEL") for benzene of 10 parts per million ("ppm"). The regulations under review would reduce this to 1 ppm. It is undisputed that there is no evidence that there is any *real,* as opposed to conjectural, difference in risk between exposure of 10 ppm and exposure of 1 ppm.

That there may be some nominal or theoretical difference in risk between the two levels of exposure can be deduced as a matter of abstract logic from the facts that (a), as the Secretary found, it is a matter of scientific dispute whether there is a safe level of exposure to any carcinogen, and (b) it is generally recognized that exposure to carcinogens at low levels is safer than exposure at higher levels. But there is no evidence at all that this putative difference, this logical construct, is other than nominal or hypothetical; no evidence that it is non-trivial, meaningful, substantial, measurable, perceptible or detectable by any method or instrumentality.[2] (Even at 10 ppm, the highest maxi-

[2] "The lack of substantial evidence of discernible benefits is highlighted when one considers that OSHA is unable to point to any empirical evidence documenting a leukemia risk at 10 ppm even though that has been the permissible exposure limit since 1971." 581 F.2d at 503, Pet. App. 18a.

mum estimate in the record was that exposure to benzene at that level entails only an infinitesimal risk of cancer; the same risk as eating two peanut butter sandwiches a week, flying round trip across the country once a month, or drinking a little more than one cup of chlorinated tap water a day. App. 174.)

There is thus no evidence that reducing the PEL from 10 ppm to 1 ppm would cure any real-world evil, or confer any real-world benefit on anyone. Nevertheless, OSHA ordered the reduction implemented—at a cost to affected private parties of some half a billion dollars at least. The Government does not dispute this lack of evidence. The Government's position rather is that OSHA has the authority to impose these regulations nevertheless.

B. The holding below.

The court below set the regulations aside. It held that the Act obliges OSHA to enact only standards that are reasonably necessary or appropriate to provide safe or healthful workplaces. 581 F.2d at 502, Pet. App. 15a. Before it regulates, said the court below, OSHA must show that a hazard exists and that its regulation will reduce the risk from the hazard. 581 F.2d at 502-503, Pet. App. 17a. In short, said the court, OSHA must have some factual basis for an estimate of expected benefits before it can determine that a one-half-billion-dollar standard is reasonably necessary. *Ibid.*

The Government distorts this holding beyond recognition. The Government would have it believed that the court below held that "the Secretary must ascertain the number of lives (and other health benefits) that the standard will save and determine whether

their value bears a 'reasonable relationship' to the cost of implementing the standard." Brief for the Federal Parties (hereinafter "Government Brief"), p. 32. It would have it believed that the court below required a "kind of tradeoff," *id.* at 71, "weighing the value of life and health against the cost of their preservation," *id.* at 55; that it required OSHA to "set the level of exposure [to toxic substances] at the point where the additional lives saved by further reduction are not worth the additional cost to save them," *id.* at 22. This is a grotesque mischaracterization. The opinion below will be searched in vain for any reference whatever to ascertainment of the number or value of lives saved, to any weighing of the value of life and health, or indeed to any "tradeoff" of any kind.

Indeed, the court below was explicit that "the agency *does not* have to conduct an elaborate cost-benefit analysis." 581 F.2d at 503, Pet. App. 17a (emphasis added); that it required no more than "*rough but educated* estimates of the extent of benefits expected." 581 F.2d at 504, Pet. App. 21a (emphasis added). Read in context, the references of the court below to a requirement that OSHA "assess the expected benefits in light of the burdens to be imposed," 581 F.2d at 503, Pet. App. 17a, that it "determine whether the benefits expected bear a reasonable relationship to the costs imposed," *ibid.*, that it "estimate the extent of the expected benefits and costs," *ibid.*, that it "estimate the extent of expected benefits in order to determine whether those benefits bear a reasonable relationship to the standard's demonstrably high costs," 581 F.2d at 504, Pet. App. 19a, that it "provide substantial evidence that the benefits to be achieved . . . bear a reasonable relationship to the costs imposed," *ibid.*, were

all merely variations on the basic theme that the Secretary cannot impose costly burdens that bring no demonstrable benefit and cure no demonstrable ill. That was the key consideration for the court below. "Before it regulates," it said, "the agency must show that a hazard exists and that its regulations will reduce the risk from the hazard. . . ." 581 F.2d at 502-03, Pet. App. 16a. It spoke in terms of requiring some showing that the regulations would do some real good; that actual, tangible, real, definable benefits—the court used terms like "discernible," "measurable," and "appreciable," 581 F.2d at 503, Pet. App. 18a—would result from the regulation; a showing based on substantial evidence, not on the "assumption that the [regulation] is likely to result in benefits" or a "deduction" that the regulation will "result in some benefit" which, if it existed at all, might be trivial, infinitesimal, *de minimis* and below the threshold of perceptibility, measurability, or significance. 581 F.2d at 503-504, Pet. App. 18a-19a.

II. The Construction Of The Act For Which The Government Contends Would Raise Significant Constitutional Questions.

It is against this background that the references by the court below to the weighing of costs against benefits must be read. And it is against this background too that that Government's position here must be viewed. The Government's argument is not merely that the Secretary need not conduct a cost-benefit analysis. The Government's argument is that the statute authorizes the Secretary to impose burdensome and costly regulations *without any showing that they address any real evil or confer any real benefit.* Thus viewed in its true light, the Government's argument does not make a

case for elaborate exegesis of statutory language, or for minute sifting of legislative history. It makes a due process case.

It is perhaps singular that a substantive due process issue in the field of business regulation should be raised before this Court more than forty years after *West Coast Hotel Co.* v. *Parrish,* 300 U.S. 379 (1937), and *United States* v. *Carolene Products Co.,* 304 U.S. 144 (1938), and more than sixteen years after *Ferguson* v. *Skrupa,* 372 U.S. 726 (1963). But it is at least equally surprising that government officials could take the position in the year 1979 that they can impose burdensome and enormously costly regulation on *no* showing of *any* rational need or justification whatever.[3] The issue the Government's construction of the Act would tender is not, be it noted, whether the challenged regulation is "unwise, imprudent, or out of harmony with a particular school of thought." *Williamson* v. *Lee Optical of Oklahoma, Inc.,* 348 U.S. 483, 488 (1955). The issue rather is whether the Government can burden private parties with enormously costly regulations on no showing of need; whether "there is some legislation with respect to which there no longer exists a means-ends test as a matter of substantive due process law," whether protected rights can "be infringed by a law having no purpose or utility whatsoever." *Moore* v. *East Cleveland,* 431 U.S. 494, 548 (1977) (White, J., dissenting).

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[3] Even the Government admits, fleetingly, that "there must be substantial evidence for concluding that a lower exposure level will be beneficial", adding that "here there was such evidence, as the court of appeals acknowledged." Government Brief, pp. 70-71. This is a fast glide over some very thin ice. The "evidence" cited by the Government was, of course, nothing more than the "deduction" or logical construct referred to at p. 3 *supra.*

We submit that, interpreted as the Government would have it interpreted, the Act could not survive constitutional scrutiny. Even under the generous modern approach to substantive due process in the context of economic regulation, it remains true that a burdensome and expensive regulation that has no rational basis denies due process. "[R]egulation which is *reasonable in relation to its subject* and is adopted in the interests of the community is due process." *West Coast Hotel Co.* v. *Parrish,* 300 U.S. 379, 391 (1937) (emphasis added). No one can say that the half-billion-dollar regulation in this case is "reasonable in relation to its subject," for no one knows what that relationship is—if any. "If the laws passed are seen to have a *reasonable relationship* to a proper legislative purpose, and are neither arbitrary nor discriminatory, the requirements of due process are satisfied. . . ." *Nebbia* v. *New York,* 291 U.S. 502, 525 (1934) (emphasis added). Preventing occupational illness is a proper legislative purpose; but no one can say that the half-billion-dollar regulation before the Court has a reasonable relationship to that purpose, for no one can say whether it has any such relationship at all. It may be "enough that there is an evil at hand for correction, and that it might be thought that the particular legislative measure was a rational way to correct it," *Williamson* v. *Lee Optical,* 348 U.S. 483, 488 (1955); but here no one can say that *in fact* there is "an evil at hand" which the measure would rationally correct. It strains language to the breaking point to say that regulation directed against an evil whose existence is only a logical construct and whose magnitude is at most nominal has any rational basis. Yet that is the import of the statutory construction for which the Government here contends.

III. The Statute Can And Should Be So Construed As To Avoid The Constitutional Question Posed By The Government's Construction.

The Court need not and should not decide this constitutional issue here. It is black-letter law that a statute should be interpreted, if fairly possible, in such a way as to free it from not insubstantial constitutional doubts. *Lynch* v. *Overholser,* 369 U.S. 705, 211 (1962); *United States* v. *Witkovitch,* 353 U.S. 194, 201-202 (1957); *Ashwander* v. *TVA,* 297 U.S. 288, 341, 348 (1936) (Brandeis, J., concurring). "[I]f a serious doubt of constitutionality is raised, it is a cardinal principle that this Court will first ascertain whether a construction of the statute is fairly possible by which the question may be avoided." *Crowell* v. *Benson,* 285 U.S. 22, 62 (1932). Here, such a construction is not only "fairly possible"; it is the only one that makes good sense on the face of the statutory language itself. It is the construction made by the court below.

In this brief we will not deal with the matter of statutory construction in any detail. It is exhaustively addressed in the brief of respondent American Petroleum Institute, and we will simply summarize its chief elements. First, the *only* delegation of rulemaking authority here involved is that contained in section 6(b) of the Act, 29 U.S.C. § 655(b). Second, that section authorizes the Secretary by rule to promulgate "occupational safety or health standard[s]"; and section 3(8) of the Act, 29 U.S.C. § 652(8), defines the standards so authorized as those which are "reasonably necessary or appropriate to provide safe or healthful employment and places of employment." Therefore, OSHA has been authorized by Congress only to promulgate rules which are "reasonably necessary or ap-

propriate" to provide safe or healthful employment. And it is inherent in the very meaning of the words that a regulation cannot be said to be "reasonably" necessary or appropriate to provide safe or healthful employment without a showing that the regulation will in fact make a "reasonable" difference in safety or health conditions; that employment *with* the regulation is, to some "reasonable" degree, safer or healthier than employment *without* it. Any other interpretation strains not only language but credulity. It is simply implausible to believe, absent absolutely clear and unambiguous language, that Congress would have sought to confer on any official the power to issue Draconian rules—and fiercely expensive ones—with no showing whatever that they would do anyone any perceptible good. Certainly, since this construction is not merely "fairly possible" but is compelled by logic and grammar alike, and avoids a not insubstantial constitutional question, it is to be preferred over the tortured construction offered by the Government.

IV. In This Case It Is Unnecessary To Address The Additional Matters Sought To Be Injected By The Government.

A. It is unnecessary to address in this case the nature and extent of any cost-benefit or cost-effectiveness analysis required by the Act.

In short, construed so as to avoid constitutional questions the statute requires that any regulations issued under it be directed at a real, not a nominal, hazard; and here no such hazard has been shown. We submit that this disposes of the case. It is not here necessary to go further and examine the extent to which the statute requires OSHA to balance the cost of regulation against actual tangible benefits, nor the extent to

which the statute requires OSHA to weigh the comparative costs of different methods of achieving a given level of protection. Nor is it necessary to review here what the court below said with respect to the weighing of costs against benefits.

This is not to say that the statute does not impose such requirements. It does. Indeed, the constitutional concept of reasonable relationship to a legitimate purpose itself embraces such considerations, for there must be a point at which the mandating of megaton-yield weaponry at private expense to kill hypothetical gnats would spill over into irrationality.[4] Indeed, only last Term, in upholding against a due process challenge the figure set by Congress as the limit of liability for nuclear power operators in the Price-Anderson Act, 71 Stat. 576, 42 U.S.C. § 2210, this Court applied just such a means-ends test by appraising the figure fixed by Congress against such factors as the need to encourage the industry and the likelihood that any losses greater than the limit would be suffered. *Duke Power Co.* v. *Carolina Environmental Study Group, Inc.*, 438 U.S. 59, 84-87 (1978). See also *California Bankers Association* v. *Shultz*, 416 U.S. 21, 50 (1974). We believe in any case that the Act itself requires such an appraisal, both in its requirement of "reasonable necessity" and in its requirement of "feasibility." This matter, again, is dealt with comprehensively in the brief of respondent American Petroleum Institute. But we submit that consideration of this issue by this Court should await a case in which the issue is fairly presented by an OSHA regulation directed at some real, demonstrated,

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[4] TVA *v.* Hill, 437 U.S. 153 (1978), cited at Government Brief, p. 41, deals with Congress's setting of the Government's own priorities, and has nothing to do with due process to private parties.

tangible risk against which the costs of the regulation might be balanced. That is not this case.

B. It is unnecessary in this case to go beyond the basic issue in other respects suggested by the Government.

This is the first case involving the substantive bounds of OSHA's rulemaking authority to be heard by the Court.[5] It is understandable therefore that the Government would seek to have the Court's opinion herein grant it a sweeping charter, and endorse its practices and policies as broadly as possible. The Government's brief accordingly touches on a number of extraneous issues, and characterizes some OSHA policies in a way with which others would not agree. We urge the Court to reject the Government's efforts to broaden the issues unnecessarily. We urge the Court to make clear in its opinion that it is dealing with OSHA's authority to regulate toxic substances only in the context of the record before it. Otherwise, cases may be prejudiced as to which the scientific evidence is quite different—such as the proceedings now pending for review of OSHA's lead and arsenic standards, to which ASARCO is a party.

We note first that this case deals with benzene, a relatively recent creation of man. The record as to such a substance has little or no necessary bearing on such quite different substances as arsenic or lead, which are naturally occurring elements to which man-

[5] Marshall *v.* Barlow's, Inc., 436 U.S. 307 (1978), involved a procedural matter, holding OSHA's practice of warrantless searches of private premises to be unconstitutional. Atlas Roofing Co. *v.* OSHA, 430 U.S. 442 (1977), also involved a procedural issue, the right to jury trial with respect to civil penalties.

kind has been exposed throughout its evolution and to which it has developed a degree of natural tolerance, so that low exposures can be borne without ill effect. Nor do OSHA's abstract deductions about carcinogens and the supposed absence of a safe level of exposure to them have any application to substances such as lead which are not even claimed to be carcinogens. We respectfully urge the Court to take care that nothing be said in its opinion herein that would prejudice the issues as to lead, arsenic, and other substances having little or nothing in common with benzene.

We note secondly there is no need here to consider whether the substantial evidence review mandated by section 6(f) of the Act, 29 U.S.C. § 655(f), for *all* the Secretary's "determinations" is nevertheless inapplicable to determinations that are clearly of a "policy" nature. See Government Brief, p. 44 note 37, at p. 45. Whether the benzene standard would produce real benefits was clearly a question that was subject to evidentiary development. The broader matter of the standard of review applicable under this statute to true policy determinations is a vexed question, about which distinguished judges of the courts of appeal have "ruminated" at length. *E.g., IUD* v. *Hodgson,* 499 F.2d 467, 472-76 (D.C. Cir. 1974) (McGowan, J.); *Associated Industries* v. *Department of Labor,* 487 F.2d 342, 347-50 (2d Cir. 1973) (Friendly, J.). It involves peculiar statutory language reflecting a compromise between House and Senate, see *Associated Industries, supra,* at 347-49. It is not a simple issue, it should not be passed upon without full briefing and

argument, it is not here presented, and it need not here be addressed.[6]

We note finally that the history of OSHA regulation has not been the story of reasoned decision-making, taking costs and benefits into rational account, that the Government brief implies; and that OSHA's policies, stated or applied, have been confused and contradictory. As the brief of respondent American Petroleum Institute points out, in annual reports and speeches and testimony by the Secretary of Labor and the cognizant Assistant Secretary, OSHA has repeatedly claimed that it was making efforts to quantify the benefits achieved by its regulation, and that it regularly performs incremental cost-benefit analyses which are a key factor considered before new regulations are issued; yet in actual published standards it has freely admitted the absence of such studies. See, *e.g.,* the Preamble to the Inorganic Lead Standard, 43 Fed. Reg. at 54427 (November 21, 1978). Again, the Government implies that OSHA has used a "risk-assessment" technique to determine "safe" levels of exposure to non-carcinogens, and has limited PEL's to levels so determined in such cases. Government Brief, p. 68 note 47. We are aware of no example of this. Rather, OSHA almost invariably concludes that no safe level exists, and mandates the lowest level achievable. Even in the inorganic lead standard, OSHA set

[6] The constitutional issue discussed in Part II of this brief, *supra,* would of course not be affected by the resolution of this question, since that issue goes to the question whether the Secretary's action bears a reasonable relationship to a legislative purpose on any interpretation of the record. Nor in any event do the cases addressing this issue support the wide-open and virtually untrammeled authority for which the Government contends here. Neither do the other cases cited at Government Brief 44-45.

the PEL drastically lower than the level at which adverse health consequences were shown to exist. 43 Fed. Reg. at 52964 (November 14, 1978) and 54427 (November 21, 1978). Again, though the Government's brief pays lip-service to the concept of "cost-effectiveness" (the consideration, that is, of the comparative cost of alternative methods of achieving a given PEL), concedes that it is mandated by Executive Order No. 12044, 43 Fed. Reg. 12661 (March 24, 1978), Government Brief, p. 67 note 55, and implies that OSHA uses it "in selecting the method by which employers must achieve the lowest feasible level of exposure," Government Brief, p. 71, we are in fact aware of no instance in which OSHA has allowed a PEL to be achieved by the use of relatively inexpensive personal protective devices rather than by costly engineering controls and work practices unless the latter were wholly unfeasible.[7]

None of these matters is before the Court in this case. Indeed, the Government concedes that issues with respect to cost-effectiveness determinations are "quite different" from those presented here. Government Brief, p. 67 note 55. These and the other issues mentioned above, however, are or may be presented in the proceedings for review of the inorganic lead and in-

[7] Thus, the inorganic lead standard, which does not even deal with a "life-threatening" carcinogen, *cf.* Government Brief, p. 42 note 35, forbids the use of personal protective devices to achieve the PEL even though recognizing that in some circumstances it can be achieved by no other means. *Compare, e.g.,* 43 Fed. Reg. 54482 (November 21, 1978) (maintenance operations) *with* 43 Fed. Reg. 53008 (November 14, 1978) (methods of compliance). *Cf.* the inorganic arsenic standard, in which OSHA flatly refused to consider the cost-effectiveness of personal protective devices against that of engineering controls. 43 Fed. Reg. 19607 (May 5, 1978).

organic arsenic standards now pending in the courts of appeal for the District of Columbia and Ninth Circuits. We, therefore, urge the Court expressly to confirm in its opinion herein that such issues are not before it in this case.

In short, the world of OSHA regulation is not the rational and orderly one that the Government's brief implies. Lurking in this tangled thicket are many issues that will come before the courts in due course on their own records, issues whose consideration should not be prejudged by the sweeping ruling sought by the Government here.

CONCLUSION

To interpret the Act as the Government would have the Court do—as conferring on an official the untrammeled and unreviewable authority to impose on private parties burdens and costs of staggering magnitude so as to secure hypothetical benefits which, if they exist at all, are not shown to be more than merely nominal in nature or infinitesimal in amount (if that)—would raise serious due process questions. Such questions can and should be avoided by a simple and straightforward construction of the Act as requiring substantial evidence that an occupational safety and health standard will result in real benefits. No further issue need or should be decided on this record.

Respectfully submitted,

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